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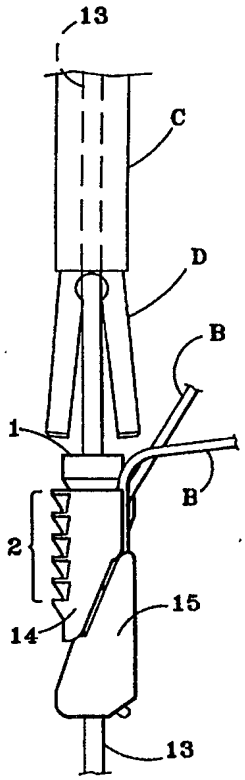
(54) Title: A SUTURE ANCHOR

(57) Abstract

One embodiment of the instant invention is made up of a guide wire component (13), a proximal wedge component (14) and a distal wedge component (15). In a second preferred embodiment, a uniquely designed surgical wedge anchor is provided having a barbed top portion (105), a plurality of suture holes (101, 102, 101b, 102b, 103, 103b) and a centrally located lower tooth (106) within a rounded notch in a lower-most portion (122).



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A SUTURE ANCHOR

Background of the Invention

Field of the Invention

The instant invention relates to that panoply of devices that serve to anchor to bone, or soft tissue, suture materials for the purpose of facilitating adherence of soft tissues such as muscle and ligament tissues in close apposition to such bone by way of such suture materials being sewn thereto and therein.

Brief Description of Related Prior Art

The following patents may bear somewhat on the essence of the instant invention. However, the instant invention represents a manifest improvement upon and variation from any other arguable similar devices current in or out of vogue within the scope of the field of such devices.

Inventor(s)	Title Invention	U.S.Patent No.	Issue Date
Goble et al	Harpoon Suture Anchor	5,141,520	8/25/92
Gatturna et al	Suture Anchor	4,898,156	2/6/90
Chow	Surgical Implement	5,176,682	1/5/93
Anspach, Jr.	Suture Anchor and Method of Forming	5,102,421	4/7/92
Fischer et al	Bone Fastener	4,716,893	1/5/88
Goble et al	Ligament Anchor System	4,870,957	10/3/89
Hayhurst et al	Bone Anchor and Method of Anchoring a Suture to a Bone	5,037,422	8/6/91

There are numerous and various types of anchor devices in existence today that are designed to facilitate the

holding of soft tissue to bone by way of holding surgical sutures sewn into such soft tissue. But, these devices and means such as screws with loops on their crowns, glues and the like are universally amenable to failure over time due to, for example, degradation of bone, breakage at joints within such devices or adhesive defects. Such failure requires readmission of affected patients to surgery and subjugation of such persons to inherent risks and inexorable expense related to the same. Hence, the essential object of the instant invention is to obviate, to the fullest possible extent, such failure.

The instant invention has no relatively delicate joint sites. One embodiment functions by way of action-reaction laterally directed and hence once wedged into place simply cannot come loose under the influence of whatever physiological load force as could conceivably be applied to it. Another embodiment functions by way of toggle movement laterally directed and hence once lodged into place cannot come loose under physiological force load.

The instant invention is, respectfully submitted, in view of the foregoing, new, indeed revolutionary within its field and unquestionably useful and unique in that it functions in a truly new and unique way as a viable anchor. Moreover, in view of its new and unique type of framework, its dependability from a standpoint of essentially non-susceptibility to breakage in situ is beyond reproach.

Also, the second embodiment of the instant invention constitutes a significant improvement, over the suture anchor of the first embodiment since, the relative complexity of and cost of manufacture of the proximal wedge component thereof exceed not insignificantly the same as respects any of the above-mentioned distal wedge embodiments. Moreover, the barbed tip and lower tooth features of the above-mentioned embodiment facilitates even more effective embedding into tissue material especially bone than does the beveled top edge of the distal wedge

component of the suture anchor especially absent the presence of that device's proximal wedge component.

Finally, the device of this second embodiment is likewise essentially non-breakable, and, for all of the foregoing reasons, respectfully stated, constitutes a new, useful, and unique advancement in the art relating to devices of this nature.

Summary of the Invention

One preferred embodiment of the instant invention is made up of three essential components. One is a so-called distal wedge. A second is a so-called proximal wedge. And, the third is a guide wire to which the first two components are fastened but amenable to removal therefrom.

A surgeon utilizes this embodiment of the instant invention by first resorting to utilization of a cannulated drill bit and drilled a hole into bone. Then the surgeon inserts the guide wire component of the instant invention through the lumen of the embedded drill bit after having first removed the drill therefrom by loosening the drill chuck and pulling the drill away. Once the guide wire is within the lumen of the bit, then the drill bit is removed by holding the guide wire with one hand and pulling out the bit with the other by way of a pincer device after having first removed the proximal wedge and distal wedge components from the guide wire component. Then the hand holding the guide wire above the removed bit is placed below the bit to continue holding the wire in place in the drilled hole while the bit is pulled up and off the wire. Then the wedge components are placed back on the guide wire after first threading suture wire through the distal wedge component and the wedge components are guided down the guide wire in the drilled hole and tamped down into place within the drilled hole. An insertion tool is utilized for such purpose. Then the guide wire component is removed from the drilled hole. Once the wedge components of the invention are in place, then downward pressure is applied

to the head of the proximal wedge component by pushing down on it with the insertion tool to push it into the drilled hole while upward pressure is applied to the suture thread previously threaded through and about the base of the distal wedge. This combination of pushing and pulling causes the distal wedge to slide upwards against the proximal wedge being pushed downward. This action of sliding upward causes the inclined medial faces of each wedge component to slide over one another and to concomitantly push each wedge component laterally out against the sides of the drilled hole. The wedge components are thus pressed firmly and permanently into place by virtue of the increase in the central diameter of the two wedge components in interfaced apposition to one another in situ after application of the combined pressures of pushing down from the top and pulling up on the sutures about the bottom of the combined wedges. The lateral portion of the proximal wedge in situ is made up of a set of serrated edges that bite into the bony side of the hole in apposition to it. The top portion of the body of the distal wedge is beveled so as to dig into the bony side of the hole in apposition to it. The medial portion of the proximal wedge in situ has two suture grooves to accommodate suture material threaded through two cylindrical holes in the medial portion of the distal wedge in situ. Suture material is threaded through one of these two cylindrical holes and out through a circular hole in the base of the distal wedge and then through a second circular hole in the base of the distal wedge and up through the body of the distal wedge and out the other of these two cylindrical holes. The base of the distal wedge component in the vicinity of the two holes in the base is inclined so as to prevent contact between suture thread passing from one circular hole to the other and the guide wire emanating from a third hole in the base. The proximal wedge has a round hole through its head and through its

body running lengthwise that terminates in the inclined medial face in the lower portion of its body. This hole is the hole through which the guide wire component is initially threaded. The medial portion of the distal wedge *in situ* has as well a hole in it, below the above-described two cylindrical suture holes, for receipt of the guide wire component that exits through the third hole in the base of the distal wedge.

The proximal wedge also has a stop face running out at a slightly obtuse angle from the angulation of its inclined medial face. The stop face by ultimately interfacing with a medially located distal wedge stop face prevents the distal wedge from sliding by the proximal wedge and thereby defeating the intended action of the two wedge components of the invention, to wit, permanent anchoring within a hole drilled in bone when upward pressure is applied to the suture thread by pulling the two ends of the thread upwards as downward pressure is applied to the head of the proximal wedge after the tamping down of the two wedges into the drilled hole. Upward pulling causes the stop face located on the medial aspect of the distal wedge to interface with the stop face of the proximal wedge to thereby prevent the distal wedge from sliding too far by the proximal wedge *in situ* and thereby preventing the desired anchoring within bone.

Another embodiment of the instant invention includes a uniquely designed surgical wedge anchor that differs markedly from any other device of a similar nature that has heretofore been known. The wedge in this preferred embodiment has a barbed top portion, three smooth surfaced sides, two suture holes in the somewhat inclined upper portion of the remaining one of its sides that is not smooth surfaced, two laterally positioned suture holes in its base each one connected to one of the two suture holes in the upper portion of its non smooth surfaced side, a first centered hole in the middle of the upper portion of

the non-smooth surfaced side which first centered hole is between and below these two suture holes, a centered hole in its base connected to the first described center hole, an inclination in its base so as to minimize drift of suture thread passing from the two lateral holes in the base to the centered hole in the base and ultimately passing through the first centered hole, and finally, a stop face that angulates outwardly from the plane of the upper portion of the wedge's non-smooth surfaced side in which the above described holes are found and that serves to separate that side's upper portion from its lower portion inclined in an plane of inclination with direction of inclination similar to the direction of inclination of the plane of inclination of this side's upper portion. The stop face also serves to interface with the inclination in the base of a second wedge when two wedges are utilized for anchoring purposes so as to prevent slippage of one over the other during the end of the anchoring process. The wedge anchor in a third and preferred embodiment reflects all of the features of the second embodiment except that additionally it has a centrally positioned barbed tooth located in an area cut out of the lowest segment of the lower portion of the wedge's non-smooth surfaced side. The wedge anchor in a fourth embodiment resembles the third embodiment but lacks any paired suture holes in either the upper portion of its non-smooth surfaced side or in the inclined portion of the wedge's base. Finally, a fifth embodiment resembles the fourth embodiment but lacks the tooth found in the fourth embodiment. A sixth embodiment wherein there is no inclination in the base of the anchor wedge is yet another useful variant. A seventh embodiment is one that resembles any of the above described embodiments but lacks a stop face. In fact, the above described preferred embodiment without a stop face is an ideal variant for purposes of serving alone as a wedge anchor. One or more of the above described wedges can be utilized to anchor soft tissue to bone by way of suture

threading during surgery or soft tissue to soft tissue by way of a suture threading during surgery. Soft tissue connotes either muscle or cartilage or ligaments, for example.

A preferred method of using the second embodiment will now be described. A hole is drilled into bone. Then a hollow insertion tool the base of which is cut at a bias with an outer circumference less than that of the drilled hole within which there is found a hollow plunger the base of which is cut at a bias with outer circumference less in measure than that of the perimeter of the lower portion of any embodiment but greater in measurement than the inner circumference of the insertion tool or the circumference of suture thread to be utilized, is resorted to for purposes of introducing one of the preferred embodiments or a plurality of these or one of these in combination with one or more of the other embodiments into the hole to serve as a suture anchor to which soft tissue can be sutured firmly in apposition to such bone. For example, suture thread is passed through the centered holes in the one or more of the latter two embodiments as might be utilized. A knot in the suture thread is tied just below the centered hole in the base of the bottom one of the embodiments to be so utilized. Then the suture material is threaded through the hollow plunger and the plunger together with threaded embodiments are encased within the hollow insertion tool. Then the system is introduced into the hole. Downward pressure is applied to the plunger and this pressure causes the embodiment or embodiments to be so used to be introduced under pressure into the hole in such bone as the insertion tool is simultaneously withdrawn from the hole then, continued downward pressure applied to the plunger coupled with upward pressure on the suture thread causes the wedges to toggle in apposition to one another thus creating an anchor. The barbed tip(s) dig into bone on one side of the hole. The lower tooth (teeth if a plurality of

embodiments some of which are fourth embodiment variants are used) gouge into the other side of the hole by virtue of such applied downward pressure. One toggle wedge, to wit, the preferred embodiment also can be used if not so powerful a suture support is desired. Prior to use of this embodiment and insertion via the method described above, suture thread is run down each of the two upper portion suture holes so that a bridge runs from one hole to the other. Strands exiting suture holes, one per hole in the base are run up the centered hole in the base and out the first centered hole. These exiting strands are then run under the thread bridge up and away from the wedge. A plurality of wedges can be used to enhance the sturdiness of the suture support depending upon the particular requirements of the surgical procedure being resorted to. If it is desired to suture soft tissue to soft tissue, then, it would not be necessary to preliminarily drill a hole. The system can be initially prepared as noted above and the insertion tool containing within it, the one or more embodiments tied to suture material and plunger can be introduced into the soft tissue by way of merely piercing the tissue. The shape of the embodiments, the manner of suturing, and if a plurality are used for anchoring, then the base inclination and stop face characteristic all cause anchoring by toggling as previously noted, upward pressure is applied to suture thread along with downward pressure on a plunger.

Brief Description of the Drawings

Figure 1 shows the three components of the first embodiment of instant invention, the proximal wedge component, the distal wedge component and the guide wire component in a perspective view.

Figure 2 is a frontal view of the proximal wedge component shown in Figure 1 that is indistinguishable from what would be a posterior view of this component.

Figure 3 is a view of the medial side of the proximal

wedge component shown in Figure 1, in respect of its positioning in situ within a hole drilled in bone.

Figure 4 is a view of the lateral side of the proximal wedge component of shown in Figure 1 in respect of its positioning in situ within a hole drilled in bone.

Figure 5 is a longitudinal cross-sectional view of the proximal wedge component shown in Figure 1.

Figure 6 is a top view of the proximal wedge component of shown in Figure 1.

Figure 7 is a perspective view of the proximal wedge component shown in Figure 1.

Figure 8 is a view of the medial side of the distal wedge component shown in Figure 1 in respect of its positioning in situ within a hole drilled in bone.

Figure 9 is a frontal view of the distal wedge component shown in Figure 1 that is indistinguishable from what would be a posterior view of this component.

Figure 10 is a view of the lateral side of the distal wedge component shown in Figure 1 in respect of its positioning in situ within a hole drilled in bone.

Figure 11 is a cross-sectional cut away view showing the beveled edge of the top side of the distal wedge component shown in Figure 1.

Figure 12 is a bottom view of the distal wedge component shown in Figure 1.

Figure 13 is a longitudinal cross-sectional view of the distal wedge shown in Figure 1.

Figure 14 is a perspective view of the medial side of the distal wedge component shown in Figure 1.

Figure 15 shows a cannulated drill bit about to be drilled into bone.

Figure 16 shows a cannulated drill bit removed from bone after a hole has been drilled into the bone and the guide wire component of the embodiment of Figure 1 inserted through the bit into the hole.

Figure 17 shows the guide wire component of the

embodiment of Figure 1 drawn through the proximal wedge component of the instant invention.

Figure 18 shows suture thread through holes in the medial face and bottom of the distal wedge component shown in Figure 1.

Figure 19 is a longitudinal cross-sectional view of the proximal and distal wedge components of the embodiment of Figure 1 through which its guide wire component and suture threads have been threaded.

Figure 20 is a perspective view of the proximal wedge component of the embodiment of Figure 1 in apposition to a cut away view of the distal wedge component of said embodiment showing its guide wire component and suture threaded through the same.

Figure 21a is a perspective view of an insertion tool, to wit, a jaw within a sleeve.

Figure 21b is a perspective view of an insertion tool, to wit a jaw within a sleeve with the sleeve retracted to permit opening of the jaw closed only under the pressure of an overlapping non-retracted sleeve.

Figure 22 is a view of the whole embodiment of Figure 1 and suture thread in the presence of an insertion tool with retracted sleeve.

Figure 23 is a view of the whole embodiment of Figure 1 and suture thread in the presence of an insertion tool with non-retracted sleeve.

Figure 24 is a perspective view of the whole embodiment of Figure 1 and suture thread in the presence of an insertion tool with non-retracted sleeve.

Figure 25 shows the whole embodiment of Figure 2 being inserted into a hole drilled in bone shown in cross-sectional view after removal of the drill bit and insertion of its guide wire component.

Figure 26 shows the whole embodiment of Figure 1 inserted into a hole drilled in bone shown in cross-sectional view subsequent to withdrawal of its guide wire

component.

Figure 27 shows a dotted facsimile of a surgeons's left index finger and thumb holding the insertion tool and pushing down on the embodiment of Figure 1 within a hole in bone shown in cross-sectional view and a dotted facsimile of the surgeon's right index finger and thumb pulling up on suture thread.

Figure 28 shows a dotted facsimile of a surgeon's left index finger and thumb holding the insertion tool and pushing down on the embodiment of Figure 1 within a hole in bone shown in cross-setional view and a dotted facsimile of the surgeon's right index finger and thumb continuing to pull up on suture thread thereby causing the distal wedge component of the said embodiment in situ to rise against the proximal wedge component thereof.

Figure 29 shows the wedge components of the embodiment of Figure 1 firmly in-situ within a hole drilled into bone subsequent to retraction of the insertion tool.

Figure 30 is an enlarged view of the wedge components of the embodiment of Figure 1 shown firmly in-situ within a hole drilled into bone with arrows illustrating force vectors outwardly and laterally directed to the sides of the hole.

Figure 31 a reduced view of Figure 29 without arrows showing suture thread tied to soft tissue to be held in apposition to the bone.

Figure 32 is a plan view of the non-smooth surfaced side of a second embodiment of the instant invention.

Figure 33 is a plan view of the top portion of the embodiment of Figure 32.

Figure 34 is a plan view of the smooth front side of the embodiment of Figure 32.

Figure 35 is a plan view of the smooth side of the embodiment of Figure 32, opposite to the side of the same shown in Fig. 32.

Figure 36 is a longitudinal cross-sectional view of the

embodiment shown in Figure 32.

Figure 37 is a plan view of the base of the second embodiment of the instant invention.

Figure 38 is a perspective view of the first embodiment of the second embodiment of the instant invention.

Figure 39 is a plan view of the non-smooth surfaced side of a third embodiment of the instant invention.

Figure 40 is a plan view of the top portion of the third embodiment of the instant invention.

Figure 41 is a plan view of the smooth front side of the third embodiment of the instant invention.

Figure 42 is a plan view of the smooth side of the third embodiment of the instant invention opposite the side of the same shown in Figure 39.

Figure 43 is a longitudinal cross sectional view of the third embodiment of the instant invention.

Figure 44 is a plan view of the base of the third embodiment of the instant invention.

Figure 45 is a perspective view of the third embodiment of the instant invention.

Figure 46 is a plan view of the non-smooth surfaced side of a fourth embodiment of the instant invention.

Figure 47 is a plan view of the top portion of the fourth embodiment of the instant invention.

Figure 48 is a plan view of the smooth front side of the fourth embodiment of the instant invention.

Figure 49 is a plan view of the smooth side of the fourth embodiment of the instant invention opposite the side of the same shown in Fig. 46.

Figure 50 is a longitudinal cross-sectional view of the fourth embodiment of the instant invention.

Figure 51 is a plan view of the base of the fourth embodiment of the instant invention.

Figure 52 is a perspective view of the fourth embodiment of the instant invention.

Figure 53 is a perspective view of an insertion device

and plunger device located within the insertion device.

Figure 54 is a cross-sectional view of an insertion device and plunger device located within the insertion device.

Figure 55 is a cross-sectional view of the fourth and fifth embodiments of the instant invention held by a piece of suture thread.

Figure 56 is a plan view of what is seen in Fig. 55 in apposition to a plunger device an in apposition to an insertion device shown in cross-sectional view.

Figure 57 is a plan view of the forth and fifth embodiments of the instant invention held by suture thread in close apposition to a plunger device show cross-sectionally within the lumen of an insertion device shown in cross-sectional view.

Figure 58 shows an insertion device prior to its piercing a piece of soft tissue. There is also shown, suture material through the top of a plunger device shown within the insertion device.

Figure 59 shown an insertion device having pierced a piece of soft tissue. There is also shown, suture material through the top of a plunger device shown within the insertion device.

Figure 60 is an enlarged plan view of the third and fourth embodiments of the instant invention held by suture thread in apposition to a plunger device in cross-sectional view within the lumen of an insertion device shown in cross-sectional view embedded within a piece of soft tissue.

Figure 61 is an isolated enlarged view of the lower portion of an insertion device shown in cross-sectional view embedded in soft tissue material within which are found the plunger device shown in cross-sectional view and part of the fourth embodiment of the instant invention when downward pressure is applied to the plunger device as the insertion device is being withdrawn.

Figure 62 is an isolate view of the barbed top portion biting into soft tissue when downward pressure is applied to the plunger device as the insertion device is being withdrawn.

Figure 63 shows the action of the second, third, fourth, and fifth embodiments of the invention in respect biting into tissue as the process referenced in Figure 62 is continued.

Figure 64 shown the further biting into soft tissue by the second, third, fourth, and fifth embodiments of the instant invention as upward pulling pressure is applied to the suture material affixed thereto.

Figure 65 is a close-up isolated view of the bite into soft tissue by the centrally positioned barbed tooth of the fourth embodiment of the instant invention.

Figure 66 is an isolated view of the resultant anchoring within soft tissue of suture material by virtue of completion of the process described in Fig. 65 above.

Figure 67 shows in plan view the manner in which suture thread can be threaded through the holes of the instant invention's third embodiment in contemplation of its being used along as a suture anchoring device.

Figure 68 shows suture material threaded as seen in Fig. 67 but in tip plan view.

Figure 69 shows suture material threaded as seen in Fig. 67 but in front plan view.

Figure 70 shows in plan view, suture material threaded through suture holes in the inclined base of the instant invention's third embodiment.

Figure 71 is a bottom plan view of what is seen in Fig. 70.

Figure 72 is a perspective view showing the manner in which suture thread can be threaded through the holes of the instant invention's third embodiment in contemplation of its being used alone as a suture anchoring device.

Figure 73 shows in plan view, the third embodiment of

the instant invention about to be inserted into the lumen of an insertion device shown in cross-sectional view.

Figure 74 shows in plan view the third embodiment of the instant invention in apposition to a plunger device shown in cross-sectional view within the lumen of an insertion device shown in cross-sectional view.

Figure 75 shows downward pressure on a plunger device shown in cross-sectional view concomitant with withdrawal of an insertion device shown in cross-sectional view within a piece of soft tissue and commencement of the toggling of the third embodiment of the instant invention.

Figure 76 shows continued downward pressure on a plunger device shown in cross-sectional view concomitant with upward pressure on suture material tied to the third embodiment of the instant invention in furtherence of the toggling of the third embodiment of the instant invention.

Figure 77 shows the third embodiment of the instant invention subsequent to completion of the process depicted in Fig. 76 wherein the third embodiment is ready to serve as an anchor within soft tissue.

Detailed Description of Preferred Embodiments

Figure 1 shows the three components of the first embodiment of the invention, guide wire 13, proximal wedge component 14, and distal wedge component 15 fastened together to thus constitute the whole of this embodiment of the instant invention. Figure 2 shows in frontal view the proximal wedge component 14 of this embodiment of the instant invention. Its cylindrically shaped head 1 is shown as well as its lateral side 2 in terms of how proximal wedge 14 is ultimately positioned as an anchor component within a hole drilled in bone which side 2 is made up of a plurality of serrated edges. Also shown is its stop face 5 extending at an obtuse angle out from the top of its inclined medial face 6 which face 6 is shown in Figure 3 and again in Figure 7. Figure 3 shows two suture grooves 3 and 3a in the medial side of proximal wedge 14,

to wit, the side of wedge 14 opposite in position to lateral side 2 once ultimately anchored in bone as well as a guide wire exit hole 4a in the medial face 6 of the proximal wedge. Figure 4 shows lateral side 2 of proximal wedge 14 as well proximal wedge 14's cylindrically shaped head 1. Figure 5 shows lateral side 2, guide wire hole 4 and stop face 5 of proximal wedge 14 in a longitudinal cross section view. Figure 6 is a top view of proximal wedge 14 in which there is seen a top view of its cylindrically shaped head 1, guide wire entry hole 4 centrally located therein and a top view of proximal wedge 14's two identical suture grooves 3 and 3a. Figure 7 is a perspective view of proximal wedge 14 wherein there is shown all of its features as depicted in Figures 2-6 inclusive. Figure 8 is a view of the medial side of the distal wedge component 15 of the first embodiment of the instant invention, to wit, that side of distal wedge 15 in apposition to the medial side of proximal wedge 14 once wedges 14 and 15 are firmly anchored in bone. Therein shown are two identical suture entry and re-exit holes 7 and 7a respectively as well as a guide wire entry hole 4b and its inclined medial face 11. Figure 9 is a frontal view of distal wedge 15 in which there is seen its beveled top edge 9 and two identical suture exit and re-entry holes, 8 and 8a respectively in the inclined face 12 of its base. Figure 11 is a cross-sectional lateral view showing the beveled top edge 9 of distal wedge 15. It should be noted that the angle of beveling is constant to each of two points in the top edge of distal wedge 15 both equidistant from the center of the top edge from which points the angle of bevel tapers to zero degrees. Figure 12 shows the inclined base face 12 of distal wedge 15 as well as guide wire exit hole 4c and suture exit hole 8 and suture re-entry 8a. Figure 13 is a longitudinal cross-sectional view of distal wedge 15 showing its stop face 10, guide wire entry hole 4b, the canal therein leading therefrom to its

guide wire exit hole 4c and dotted lines depicting the locus of the canal therein from its suture entry hole 7 to its suture exit hole 8. Figure 14 shows distal wedge 15 in perspective view wherein there is to be seen its suture entry hole 7, its suture re-exit hole 7a, its guide wire entry hole 4b, its stop face 10 and its medial face 11. Figure 15 is a view of a piece of bone E into which a hole is to be drilled with resort a cannulated drill bit A. Once a hole is drilled into bone E, the drill which was used is separated from the cannulated drill bit A and guide wire component 13 is threaded through the canal in drill bit A. Guide wire 13 is threaded down to the base of the drilled hole typically drilled deep enough into bone to pass into deep bone F below the outer cortex E of the bone. Figure 16 shows in cross-sectional view, bone cortex E and a deeper layer F of bone. The arrow in Figure 16 shows removal to the drill bit A from guide wire 13 after proximal wedge 14 and distal wedge 15 have first been removed therefrom prior to their being repositioned as they would be on guide wire 13 once drill bit A is fully removed therefrom. Figure 17 shows guide wire 13 passing through guide wire entry hole 4 in the cylindrically shaped head 1 of proximal wedge 14 and out through its guide wire exit hole 4a. Figure 18 shows suture thread B passing through suture entry hole 7 of distal wedge component 15 and down through the canal between hole 7 and suture exit hole 8 from which suture thread B emanates before reentering distal wedge 15 through suture re-entry hole 8a and suture re-exit hole 7a from which it emanates. Figure 19 shows in cross-sectional view, guide wire 13 coursing through guide wire entry hole 4 in head 1 of proximal wedge 14 down through the canal therein leading from hole 4 to guide wire exit hole 4a and into guide wire entry hole 4b in distal wedge 15 and down through the canal therein leading from hole 4b to guide wire exit hole 4c in the base of the distal wedge. There is also to be noted in Figure 19

suture thread B as it would be found passing via suture groove 3a found on the side of proximal wedge 14 opposite the lateral side 2 thereof and into suture entry hole 7 of distal wedge 15 and out suture exit hole 8 thereof. That which is depicted in Figure 19 is depicted in part in Figure 20 as well. Figure 21A shows an insertion tool with a retractable sleeve C. Figure 21B shows sleeve C of the insertion tool retracted so that its jaw D opens. Figure 22 shows guide wire 13 threaded through the insertion tool and proximal wedge 14 and distal wedge 15 and coursing beyond them as it would be leading to the bottom of the previously drilled hole. Figure 23 shows sleeve C of the insertion tool engaged over its jaw D in preparation for pushing down on head 1 of proximal wedge 14. Figure 24 depicts in perspective view what is shown in Figure 23. Figure 25 shows guide wire component 13, proximal wedge 14 and distal wedge 15 components of the first embodiment of the instant invention in apposition to the hole previously drilled into bone cortex E wholly circumscribing deeper bone F and the arrow therein shown depicts the direction of its insertion into the bone. Figure 26 shows wedge components 14 and 15 of the first embodiment of the invention after having been pushed with the insertion tool into the hole previously drilled in bone and the arrow therein shown depicts the direction of removal of guide wire 13 once wedge components 14 and 15 are positioned in the hole previously drilled in bone. At this juncture, it should be noted that proximal wedge 14 and distal wedge 15, previously threaded with suture thread B as described above and repositioned on guide wire 13 below an insertion tool after guide wire 13 would have first been threaded through a cannulated drill bit into a hole drilled in bone and the cannulated drill bit removed from the hole and slipped up and off guide wire 13, are ready for permanently wedged insertion into the hole drilled in bone by way of the combined actions of pushing down on the head 1 of proximal

wedge 14 in-situ with the insertion tool while at the same time pulling up on suture thread B. Figure 27 shows the left thumb G and left index finger H of a surgeon pushing down on the head 1 of proximal wedge 14 with the insertion tool with downward force and Figure 27 also shows the right thumb I and right index finger J of the surgeon beginning to pull on the two strands of suture thread B that were previously shown passing through suture entry hole 7 of distal wedge 15 out its suture exit hole 8 passing therefrom along its inclined base face 12 and back through its suture re-entry hole 8a of and up through the distal wedge 15 and out its suture re-exit hole 7a. Inclined base face 12 of distal wedge 15 serves to prevent suture thread B from coming into contact with guide wire 13 as it would be emanating from hole 4c in the base of distal wedge 15. Figure 28 shows the same digits of the same surgeon pushing down with the insertion tool on head 1 of proximal wedge 14 and simultaneously pulling on suture thread B. Figure 29 shows how the two wedge components 14 and 15 of the first embodiment of the invention are positioned together and firmly anchored within the hole previously drilled in bone once the surgeon has completed the above-described process of pushing and pulling. Figure 30 is a blown up view of the inserted wedge components 14 and 15 of the first embodiment of the instant invention. The arrows M,N and O depict how force emanates laterally against the walling of the hole drilled in bone as a result of downward force L applied to head 1 of proximal wedge 14 being combined with upward force K due to the pulling up on the strands of suture thread B. The combined pushing and pulling causes the plurality of serrated edges of lateral side 2 of proximal wedge 14 to bite firmly into the bone adjacent thereto in view of the resultant upward sliding action of distal wedge 15 against proximal wedge 14 whereby the inclined face 6 of proximal wedge 14 previously in apposition to the medial aspect of distal wedge 15 comes

into interfaced contact with the inclined face 11 of the distal wedge 15 such that the central diameter of the two wedge components 14 and 15 in apposition to one another is significantly increased. Also, beveled top side 9 of distal wedge 15 cuts into bone in apposition to it in response to such concomitant pushing and pulling to thereby contribute to anchoring and beveled to side 9 together with stop face 5 of proximal wedge 14 and stop face 10 of distal wedge 15 serve to prevent either wedge from sliding by the other during the application of forces L and K to thereby serve to defeat the intended purpose of increasing the central diameter of the two wedge components 14 and 15 in apposition to one another which increasing of the central diameter is what causes the laterally directed biting and cutting described above which in turn is responsible for the permanent positioning in the hole drilled in bone of wedge components 14 and 15 of the invention, to thus result in a firmly and permanently situated suture anchor in bone. Figure 31 shows human or other animal soft tissue P held fast to bone by suture thread B tied thereabout such tissue P and concomitantly threaded through and about the distal wedge component 15 of the firmly and permanently situated instant suture anchor.

Figure 67 is a plan view of the side of the second preferred embodiment of the instant device that is characterized by the presence of the device's two suture entry holes, hole 101 and hole 102, its suture exit hole 103b, its barbed tip 105 located in its top portion and its centrally located lower tooth 106 within a rounded out notch 107 in the lowest part of the lower portion 122 of this side, to wit, of the device's only side that has holes in it. Barbed tip 105 located in the device's top portion serves to pierce into tissue on one side of a pierced insertion hole opposite to the side of the hole bitten into by lower tooth 106 as seen in Figure 77 after the embodiment is threaded as shown with suture material C' and

suture material C' is threaded through a hollow plunger B', an example of which is seen in Fig. 73 and then inserted along with plunger B' into the lumen of insertion device A' as shown in Fig. 74, and then after soft tissue D' is pierced with insertion device A' and then downward pressure is applied to plunger B' as insertion device A' is withdrawn as seen in Fig. 75 followed by continued downward pressure on plunger B' and upward pressure on suture material C' as shown in Fig. 76. Once anchoring in soft tissue D' is accomplished as shown in Fig. 77, then soft tissue D' is amenable to being sutured to to the soft tissue in close proximity thereto with virtually no fear that the sutured tissues will later come apart due to failure of suturing to hole the tissues together. Fig. 68, Fig. 69, Fig. 70 and Fig. 71 show how suture material C' is threaded through suture entry holes 101 and 102 and down through the body of the embodiment and out through suture exit holes 101b and 102b respectively in the inclined portion of the base 124 of the embodiment and then out through suture exit hole 103b located in the upper portion 120 of the side of this embodiment characterized by the presence of suture entry holes 101 and 102 with hole 103b located between and below holes 101 and 102. The nexus 102a between holes 102 and 102b and the nexus 103a between holes 103 and 103b are seen in Fig. 43. Rotation of Fig. 43 through an angle of 180 degrees would disclose a separate nexus between holes 101 and 101b equivalent in dimension to that of nexus 102a. It has been noted to be the case that it is singularly important to run the ends of suture material C' exiting hole 103b under the arch or suture material C' formed when suture material C' is initially threaded through holes 101 and 102 in order to minimize the toggling effect on the embodiment as suture thread C' is pulled upwards with downward pressure applied to plunger B' as seen in Fig. 76. Fig. 75 shows in perspective view what is depicted in Fig. 67.

Figs. 39-45 inclusive excepting Fig. 43 depict the various views of the preferred embodiment of the instant invention as are seen in Fig. 67-72 inclusive but without the suture material C' threaded through the various holes present within the embodiment. Figs. 32-38 inclusive depict various view of another embodiment of the instant invention. This latter embodiment lacks the centrally located lower tooth 106 and notch 107 of the preferred embodiment. This other latter embodiment can be utilized in conjunction with the preferred embodiment, for example, for embedding in bone when one might be seeking to hole a grater tissue load than an anchor made up of only one wedge embodiment, to wit, the preferred embodiment alone. As might be expected, two exemplars of the preferred embodiment could be utilized for purposes of constructing such a relatively stronger anchor. This latter embodiment does not have the overall holding capacity of the preferred embodiment, but, it is somewhat less expensive to manufacture due to its relative simplicity of design. Figs. 46-52 inclusive depict yet a fourth embodiment of the instant invention. This fourth embodiment is simpler in design than the former two and is less expensive to manufacture. An even simpler embodiment, to wit, the lowe of the two embodiments utilized for anchoring purposes as seen in Fig. 56 and 57 resembles the fourth embodiments but lacks the centrally located lower tooth 106 and notch 107 of the third embodiment. These latter two embodiments lack paired lateral suture holes 101 and 102 and paired suture holes 101b and 102b on the bases of these embodiments and correspondingly lack as well nexus' between holes 101 and 101b, to wit 101a and between holes 102 and 102b, to with 102a. Figs. 53-57 inclusive demonstrate how these latter two embodiments would be tied together with suture material C', placed below plunger B' through which suture material C' would have been threaded and placed in-toto within the lumen of insertion device A'. Device A' is then inserted

into tissue D' as per Figs. 58, 59 and 60. Withdrawal of the device A' coupled with downward pressure on plunger B' constitutes commencement of the process that ultimately causes the wedge system to be toggled wedged into tissue D'. Barbed tip 105 pierces into tissue D' as seen in Figs. 61 and 62. Fig. 63 illustrates the commencement of such toggle anchoring with withdrawal of device A' coupled with downward pressure on plunger B'. Fig. 64 shows completion of toggle anchoring with upward pulling pressure on suture thread C' as plunger B' is concomitantly withdrawn. Fig. 65 shows in isolated view, tooth 106 having bitten into tissue D' on the wall of tissue D' opposite to the wall pierced by barbed tip 105. Fig. 66 shows a fully constructed suture anchor with the inclined base of one wedge in apposition to the stop face 104 of a second wedge. The preferred embodiment threaded as shown previously could have been utilized in lieu of the fifth embodiment as shown in Figs. 58 through 66, and for the matter so could have the embodiment shown in Figs. 32-38 inclusive above if threaded as shown in Figs. 67 and 72, but simplicity of design and diminished cost of manufacture would be factors that would, no doubt, prompt use of the fourth and fifth embodiments for purposes of accomplishing sturdy toggle anchoring in tissue in excess of the sturdiness to be appreciated form use of the preferred embodiment alone as per the protocol evidenced with respect to Figs. 73-77 inclusive. The preferred embodiment and its less expensive counterpart, to wit, the embodiment shown in Figs. 32-38 could however be used in tandem to accomplish extra sturdy anchoring in bone.

CLAIMS

What is claimed is:

1. A suture anchor for securing a suture (B) to a bore hole in a bone (E,F), and comprising:

a. a distal wedge (15) for being removably mounted on a guide wire (13), said distal wedge including holes (7,7a,8,8a) for receiving said suture ; and

b. a proximal wedge (14) for being removably mounted on said guide wire, said proximal wedge including grooves (3,3a) for receiving said suture received through said holes of said distal wedge;

and wherein, said wedges include means (2,5,9,10) for laterally anchoring said anchor into said bone upon application of upwardly acting force (K) to said distal wedge and downwardly acting force (L) to said proximal wedge.

2. A suture anchor according to claim 1, wherein said distal wedge (15) includes a beveled portion (9) for digging into said bone.

3. A suture anchor according to claim 1, wherein said lateral anchoring means includes a plurality of serrated edges (2) on a lateral portion of said proximal wedge.

4. A suture anchor according to claim 1, wherein said wedges include stop faces (5,10) adapted to mitigate sliding of said wedges over one another upon application of said forces.

5. A suture anchor according to claim 1, wherein said wedges comprise mounting holes (4,4a,4b,4c) for receiving said guide wire, whereby to mount said wedges of said guide wire.

6. A suture anchor according to claim 1, wherein said holes for receiving suture thread comprise two holes (7,7a) in a medial portion (11) of said distal wedge and two holes, (8,8a) in a base portion (12) of said distal wedge, said holes communicating with each other through said distal wedge.

7. A suture anchor according to claim 6, wherein said base portion (12) of said distal wedge is wedge-shaped.

8. A suture anchor, and comprising, an upper (120) and lower (122) portion, said upper and lower portions including means (105,106) for piercing into body tissue (D'), and a plurality of holes (101,102,101b,102b,103,103b) for receiving suture thread (C'), said holes being located in both said upper and lower portions, at least some of said holes being connected together so as to permit said thread to be channeled through said anchor for attaching to said anchor whereby to permit said thread to be secured to said body tissue (D').

9. A suture anchor according to claim 8, wherein said anchor is wedge-shaped.

10. A suture anchor according to claim 8, wherein said anchor includes a barbed top portion (105).

11. A suture anchor according to claim 8, wherein said plurality of holes includes:

i. two suture holes (101,102) in said upper portion;

ii. two laterally positioned suture holes (101B,102B) in a base portion of said body, one of said laterally positioned holes being connected to one of said holes in said upper portion, the other of said laterally positioned holes being connected to the other of said holes in said upper portion;

iii. a first centered hole (103B) between and below the suture holes in the upper portion; and

iv. a second centered hole (103) in said base portion and connected to said first centered hole.

12. A suture anchor according to claim 8, wherein said anchor includes an angled base portion (106,107).

13. A suture anchor according to claim 8, and further comprising, a centrally positioned barbed tooth (106).

14. A suture anchor according to claim 13, wherein said barbed tooth (106) includes a notch (107).

15. A suture anchor according to claim 14, wherein

said plurality of holes includes:

i. a first centered hole (103B) between and below the suture holes in the upper portion; and

ii. a second centered hole (103) in a base portion of said body and connected to said first centered hole.

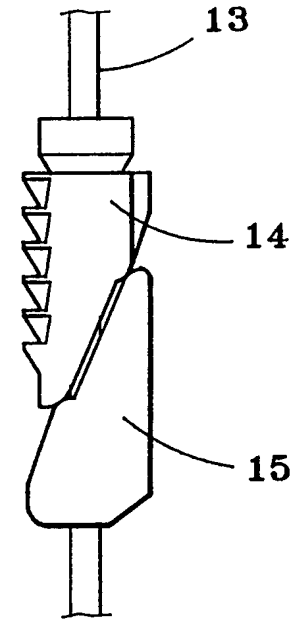


FIG. 1

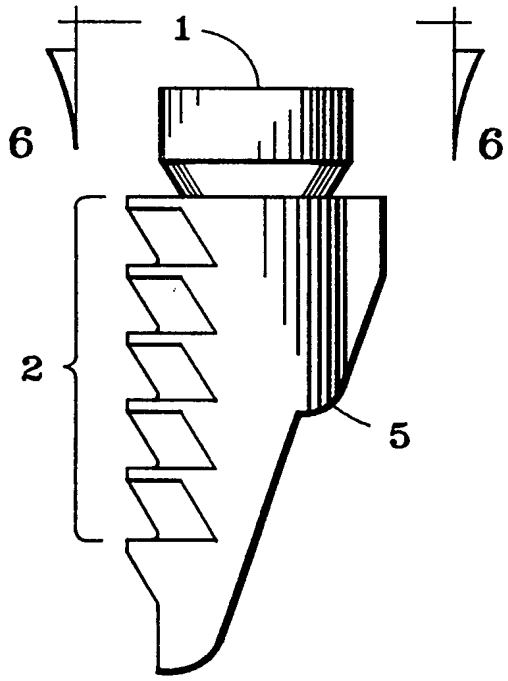


FIG. 2

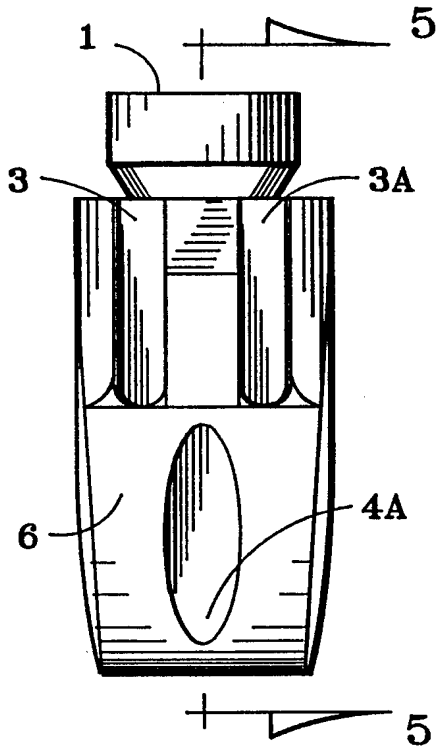


FIG. 3

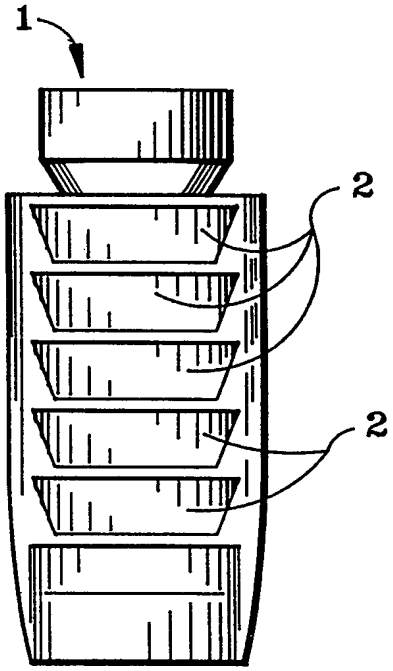
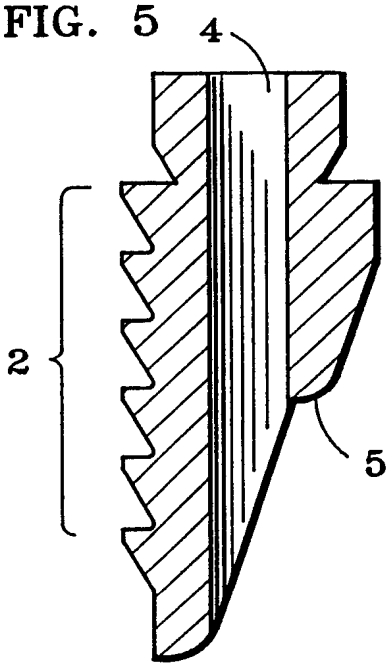


FIG. 4

FIG. 5



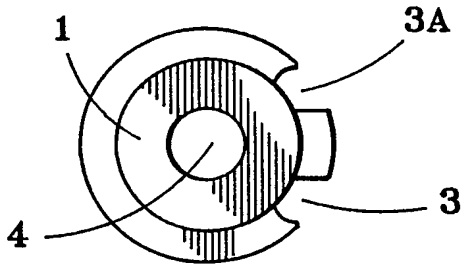


FIG. 6

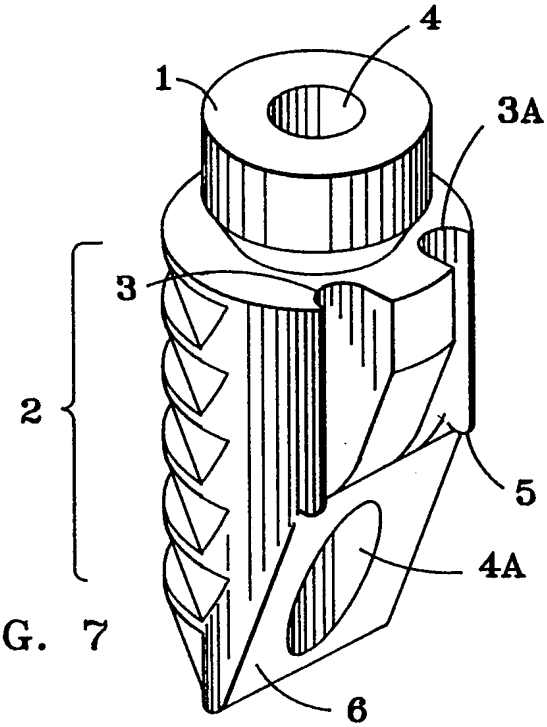


FIG. 7

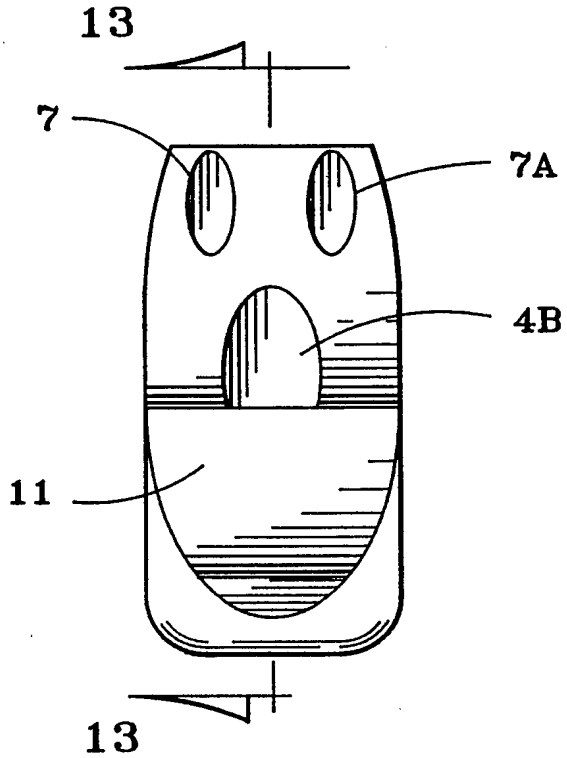


FIG. 8

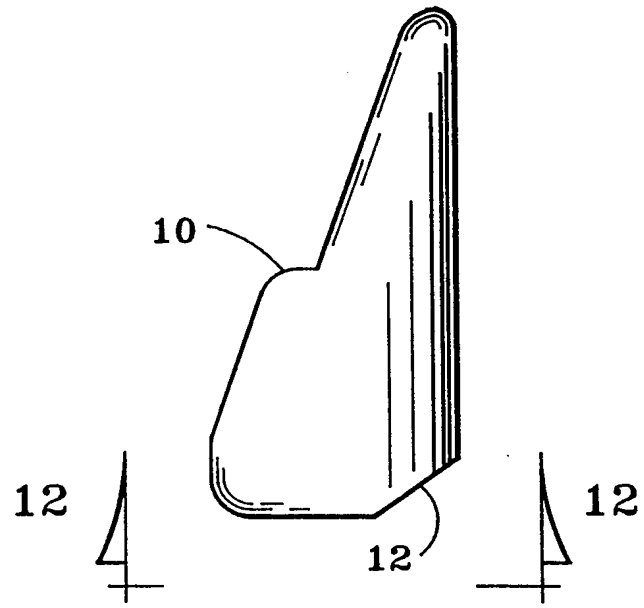


FIG. 9

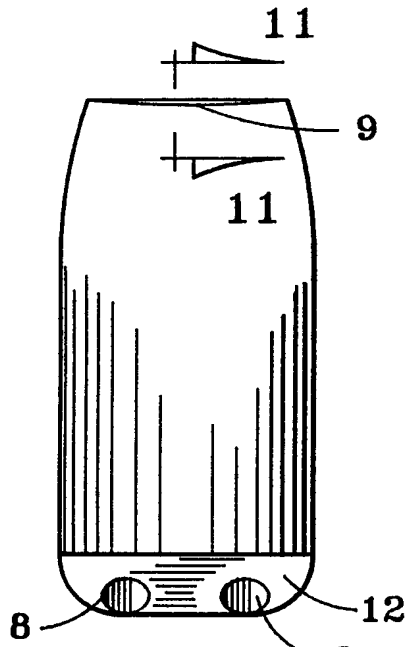


FIG. 10

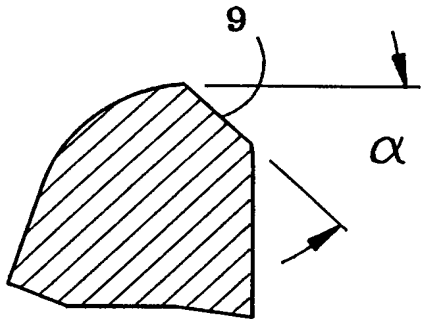


FIG. 11

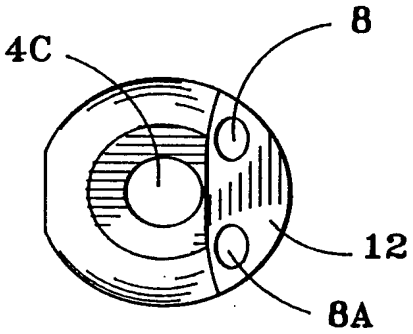


FIG. 12

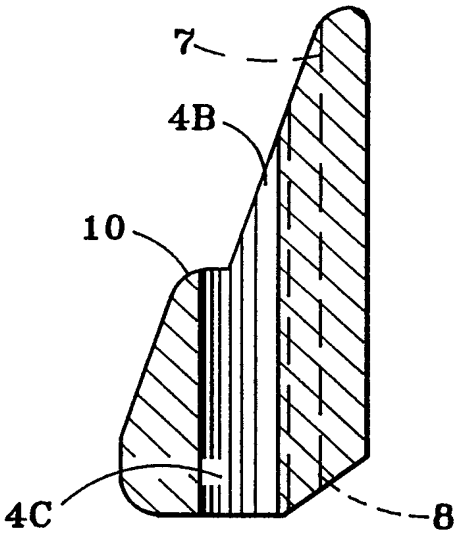


FIG. 13

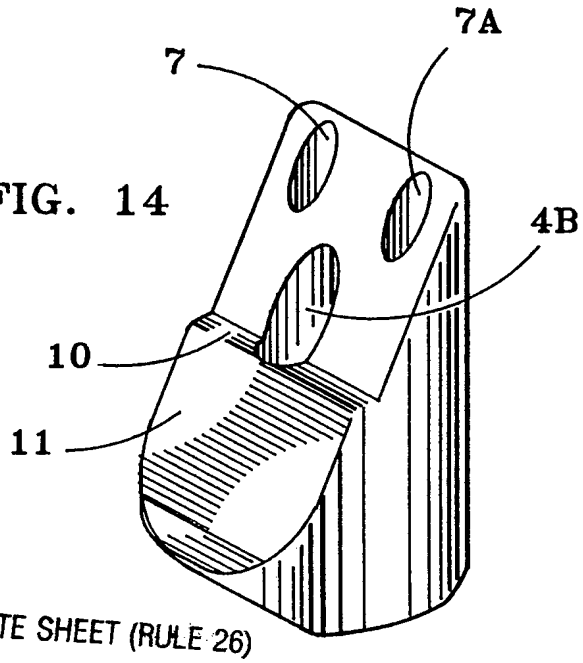


FIG. 14

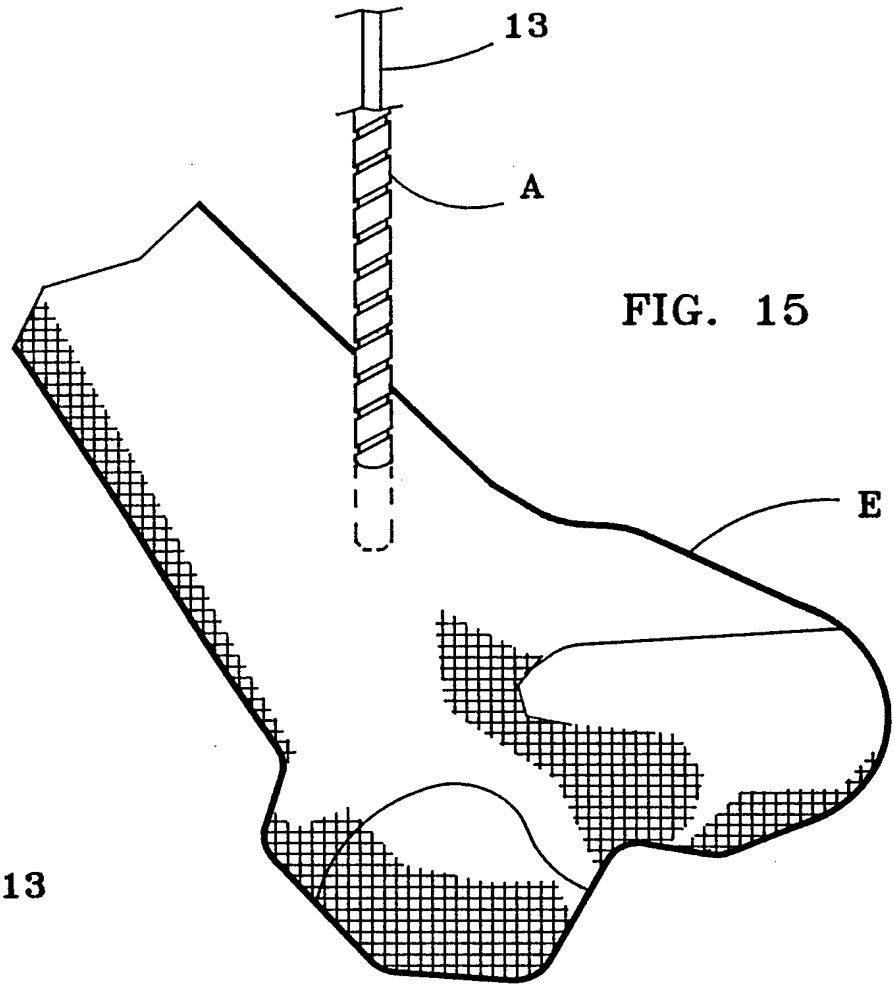


FIG. 15

FIG. 16

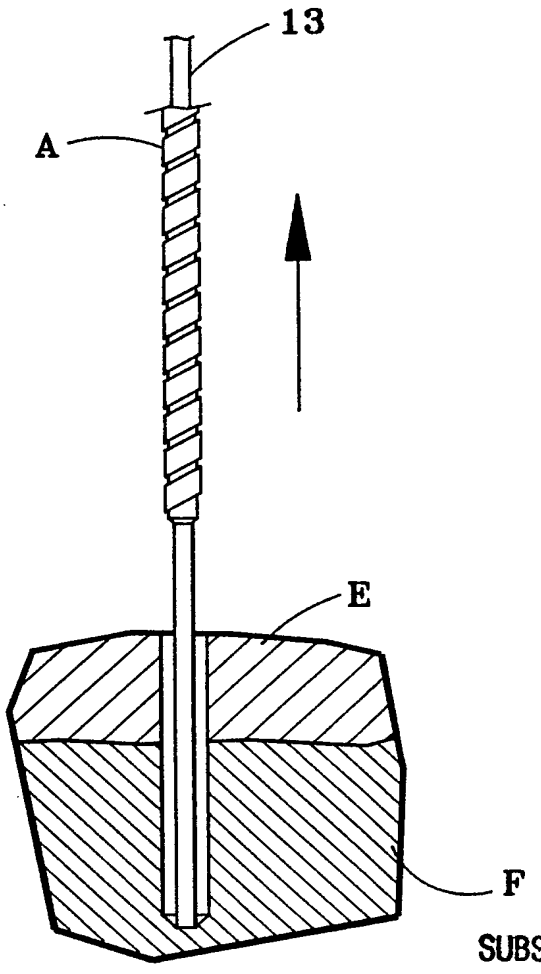
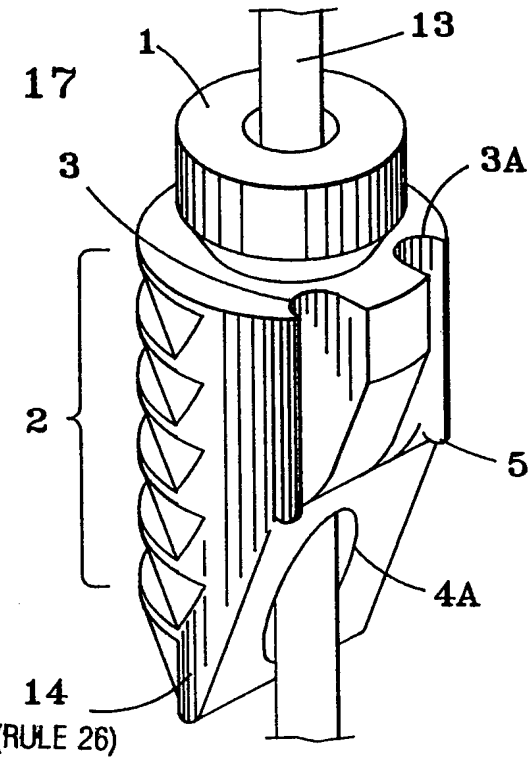


FIG. 17



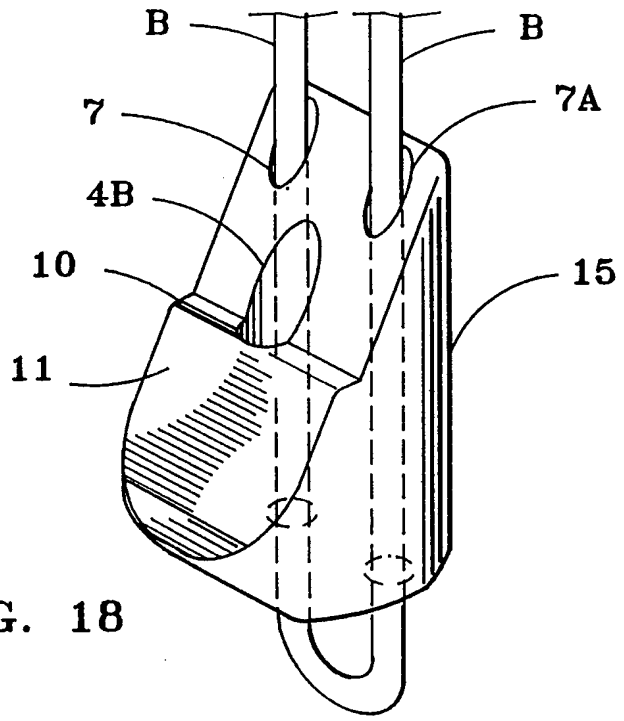


FIG. 18

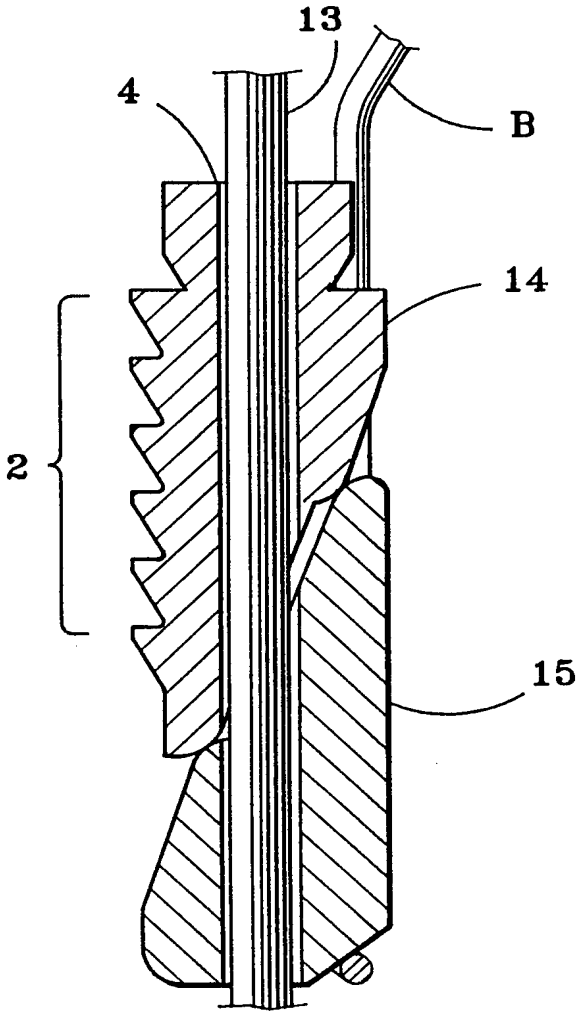


FIG. 19

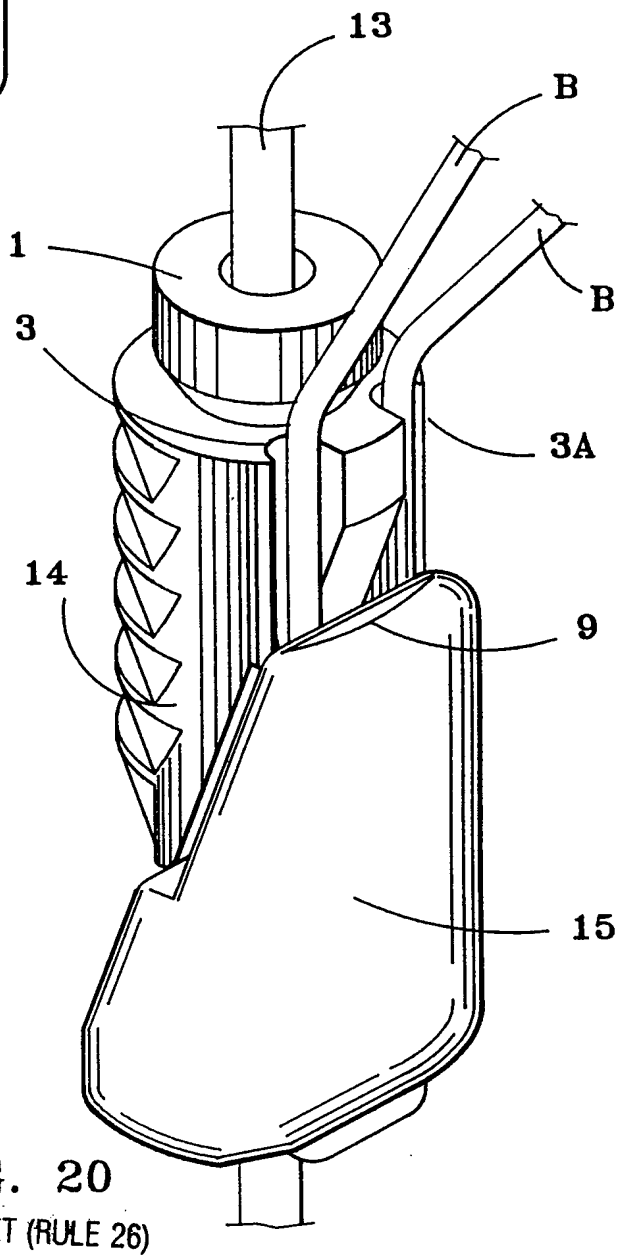


FIG. 20

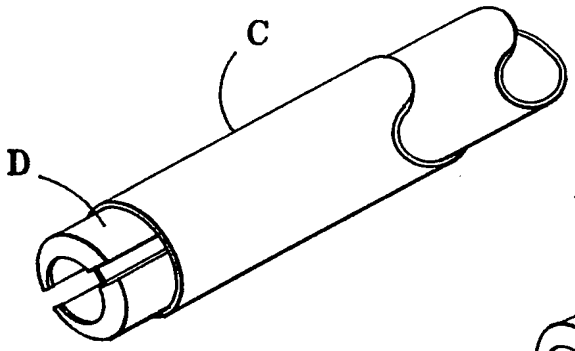


FIG. 21A

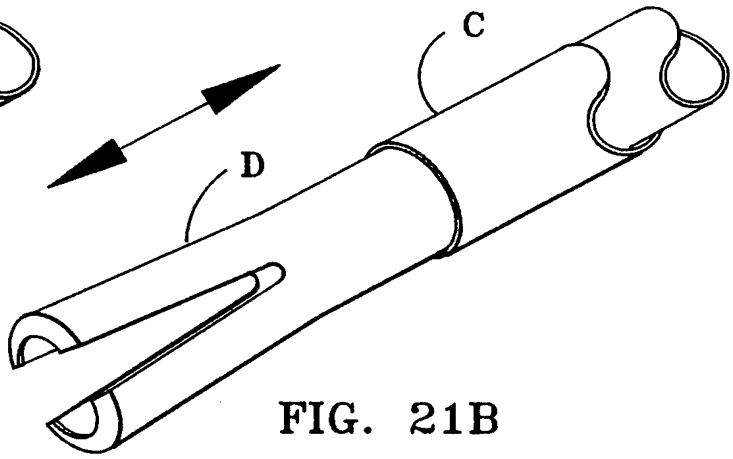


FIG. 21B

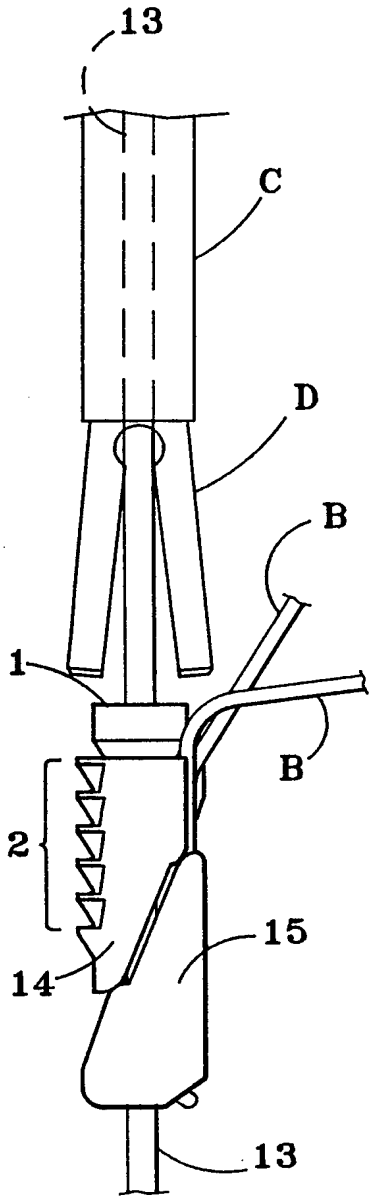


FIG. 22

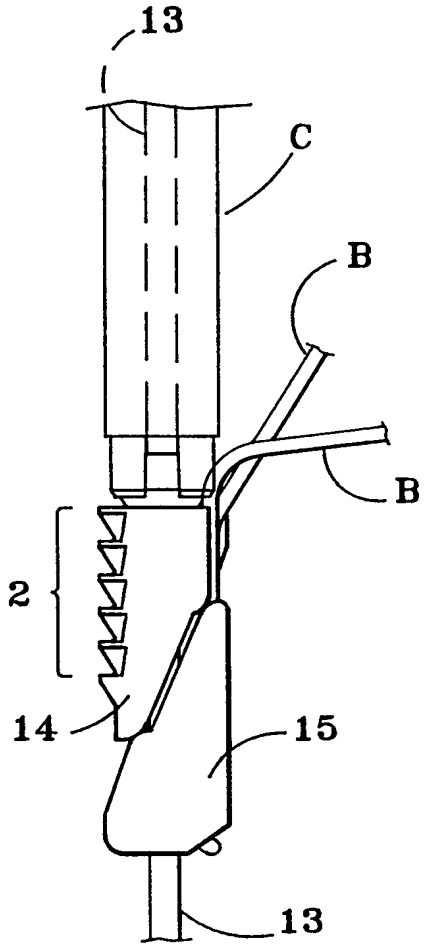


FIG. 23

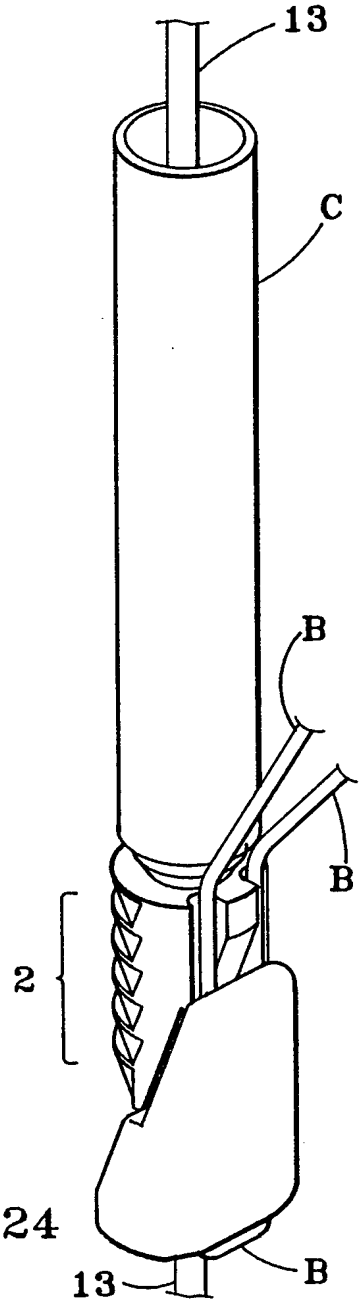


FIG. 24

FIG. 25

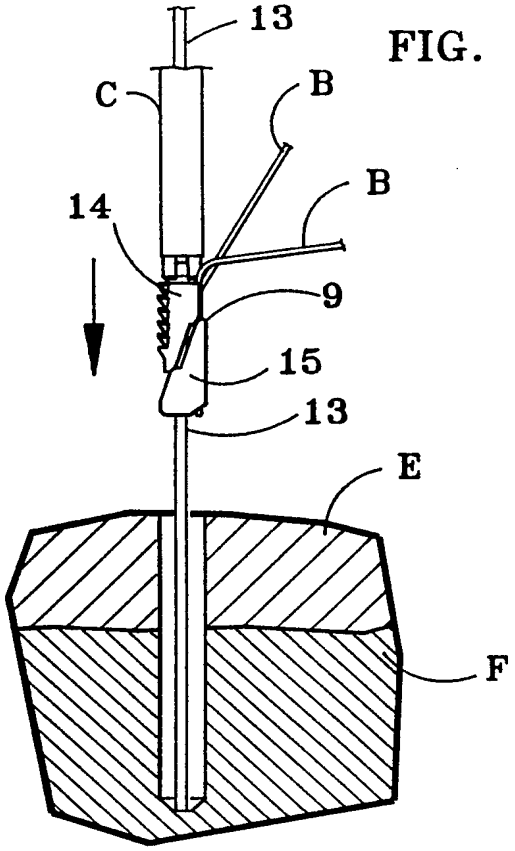


FIG. 26

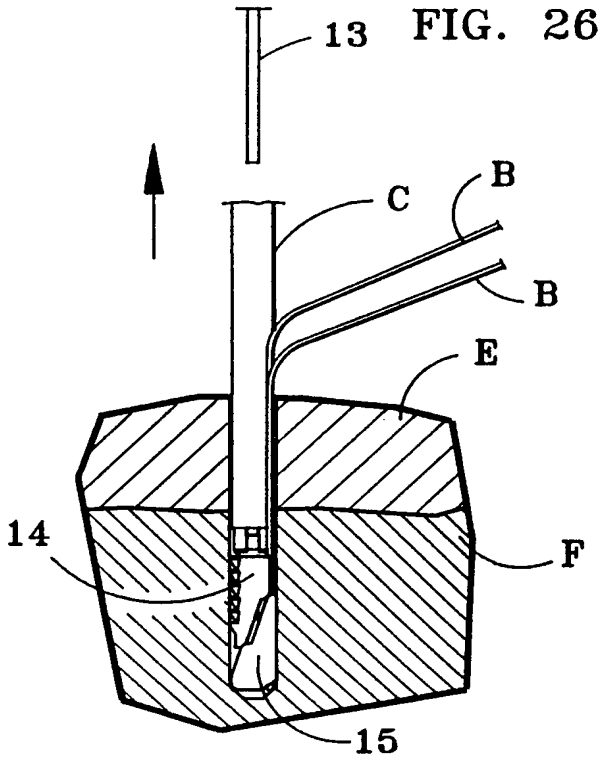
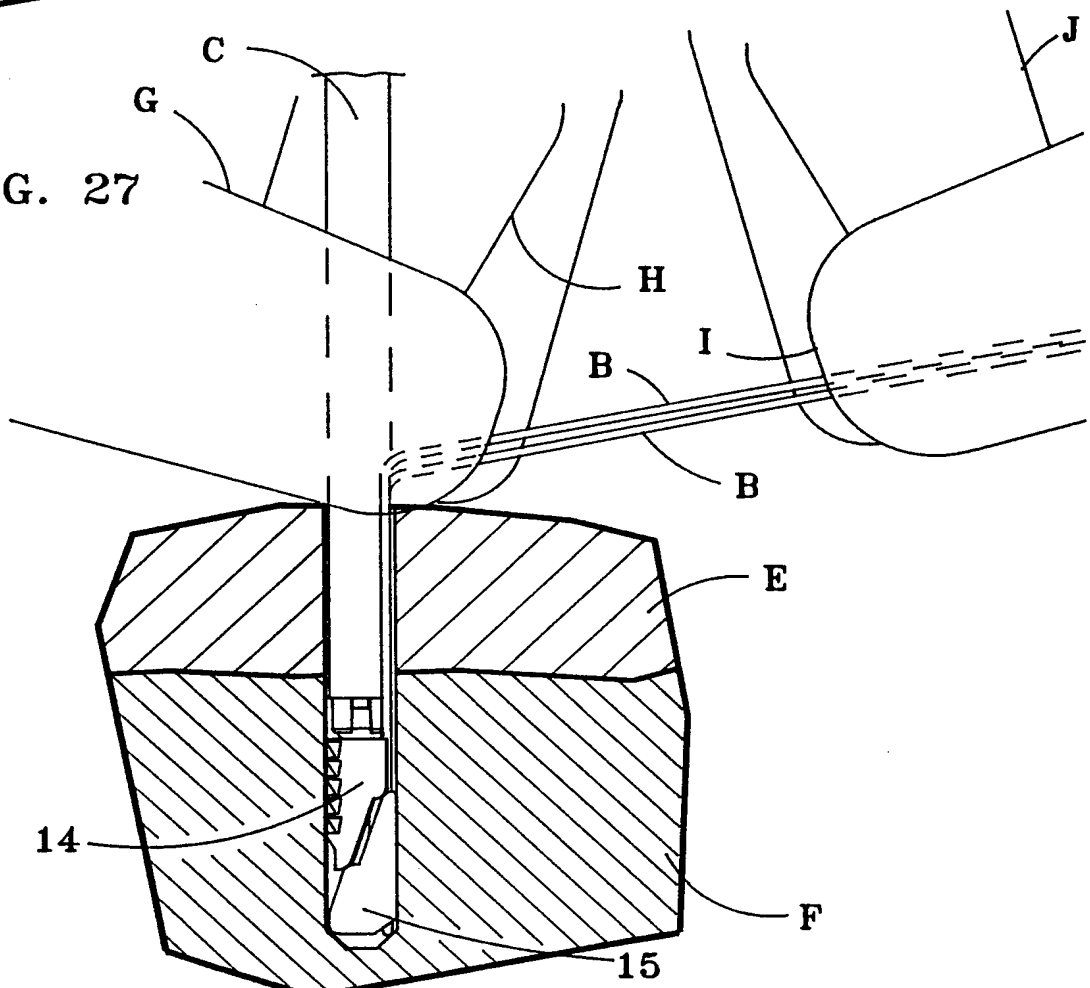


FIG. 27



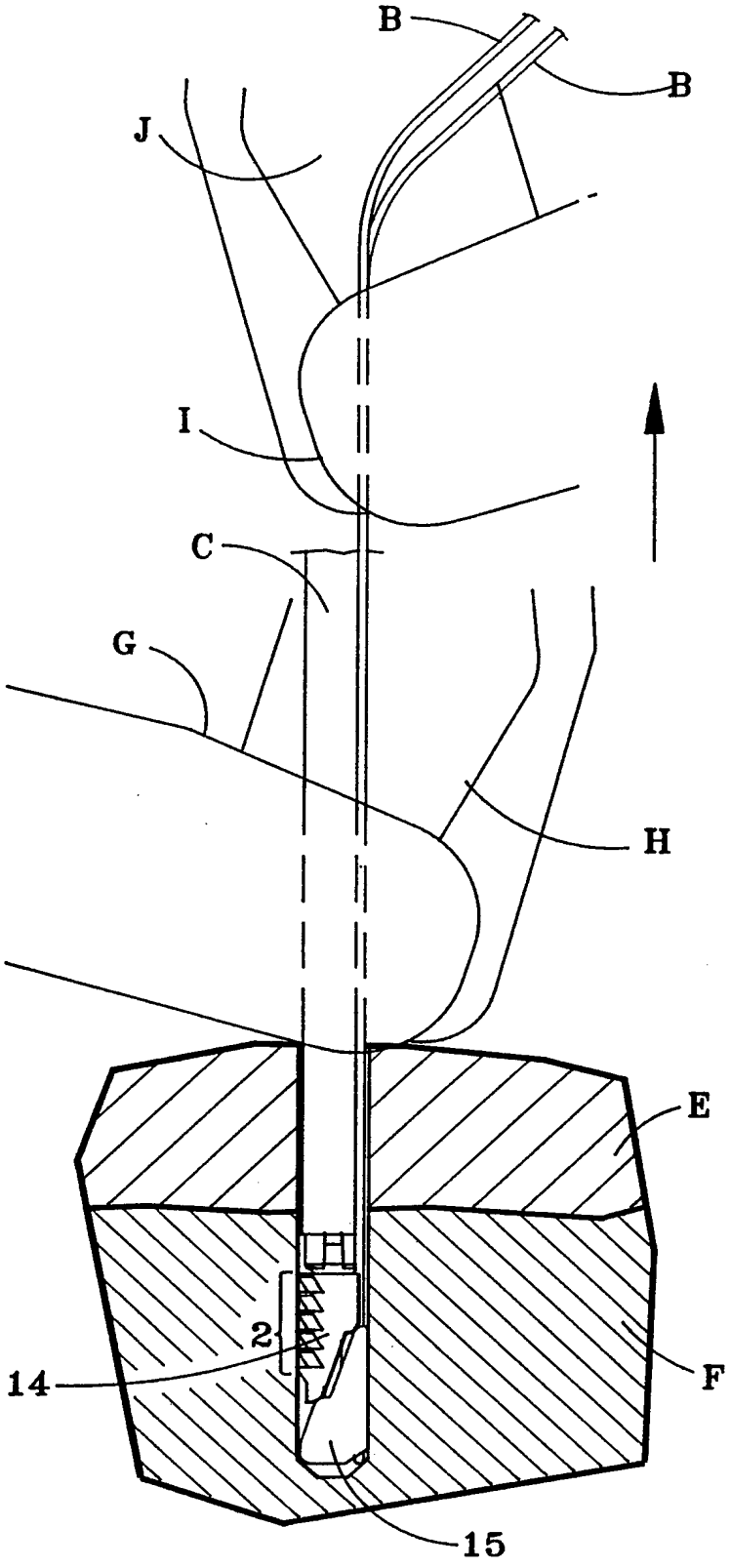


FIG. 28

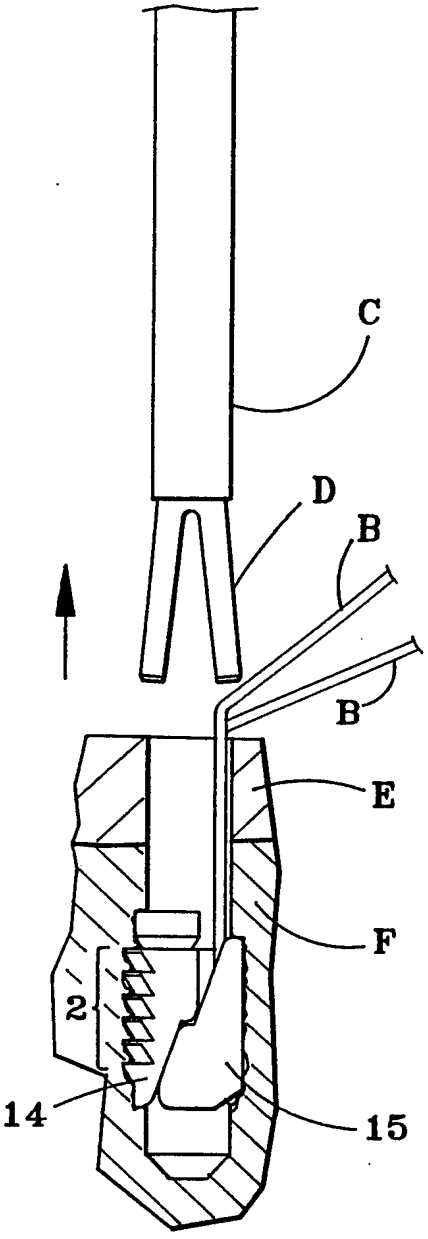


FIG. 29

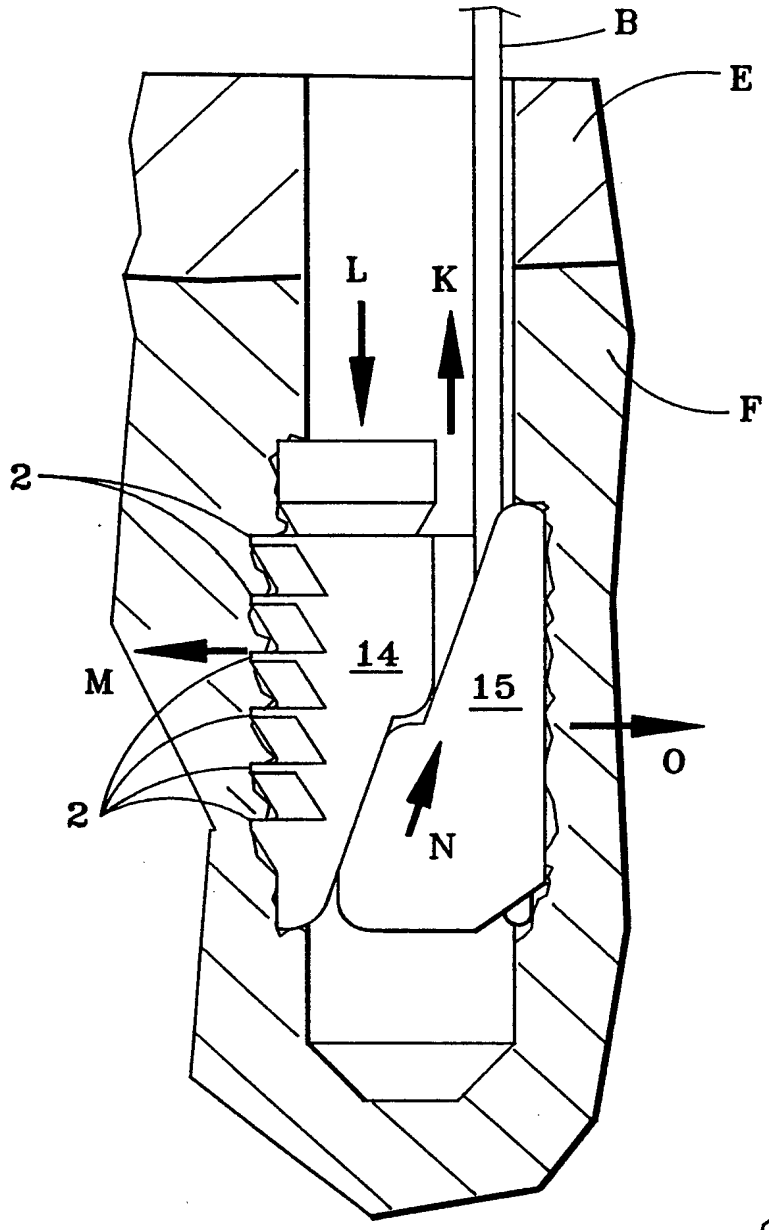


FIG. 30

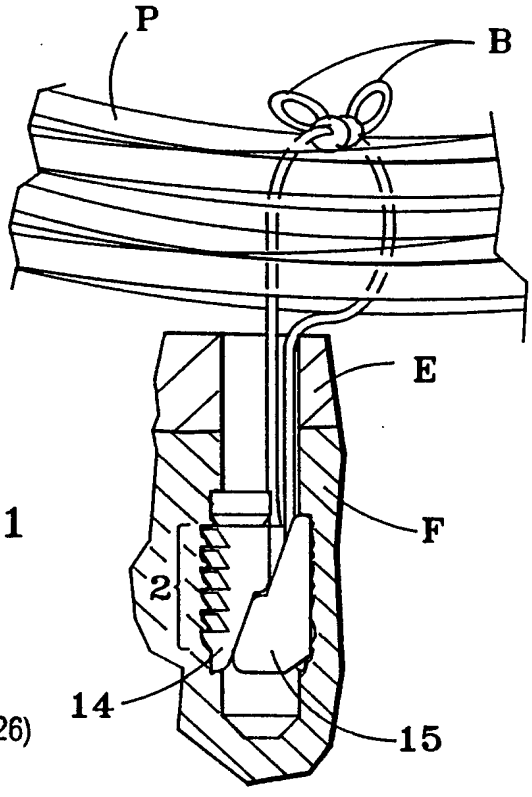


FIG. 31

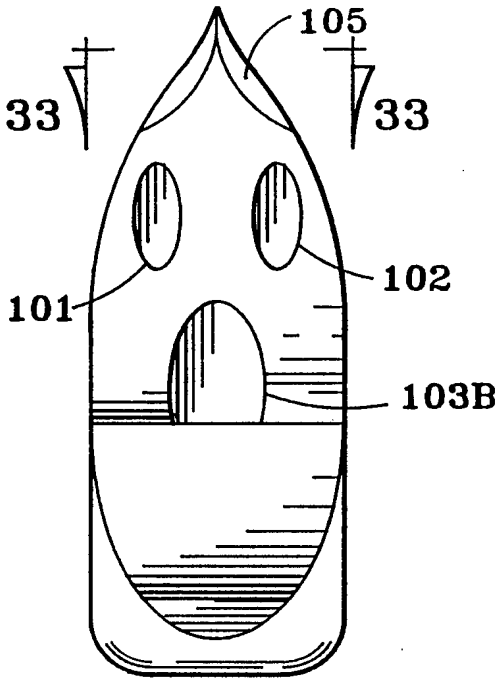


FIG. 32

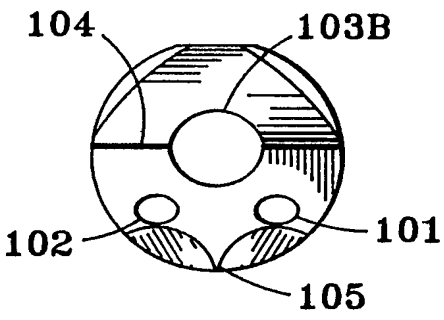


FIG. 33

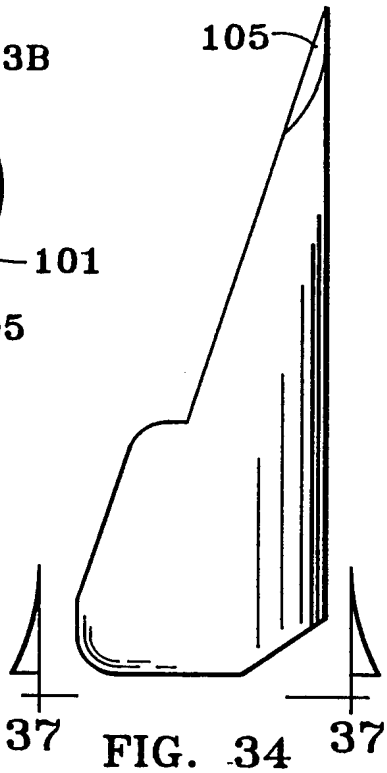


FIG. 34

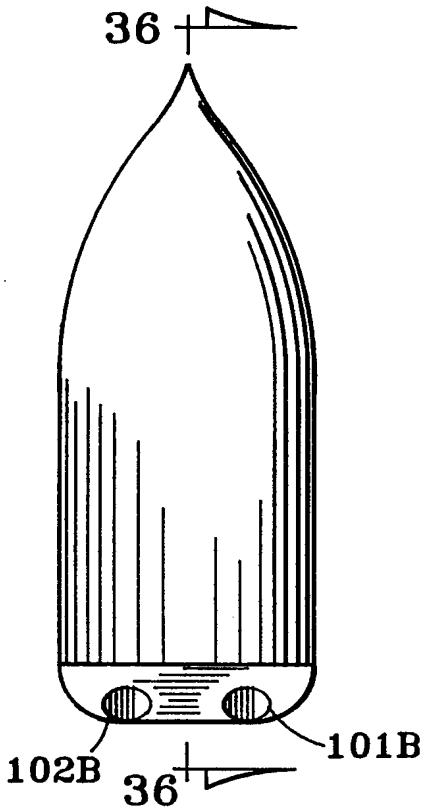


FIG. 35

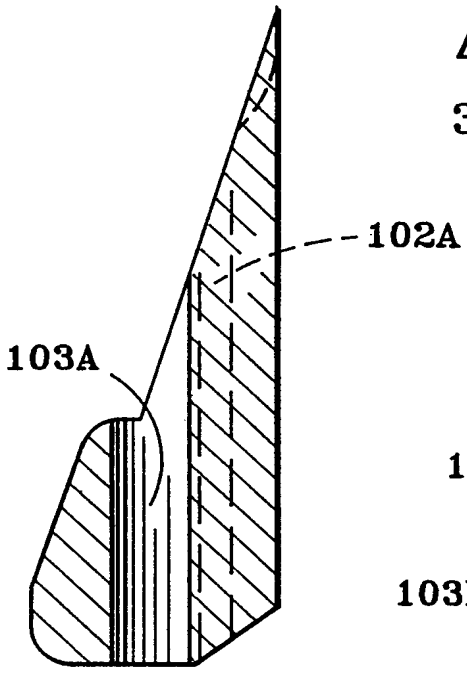


FIG. 36

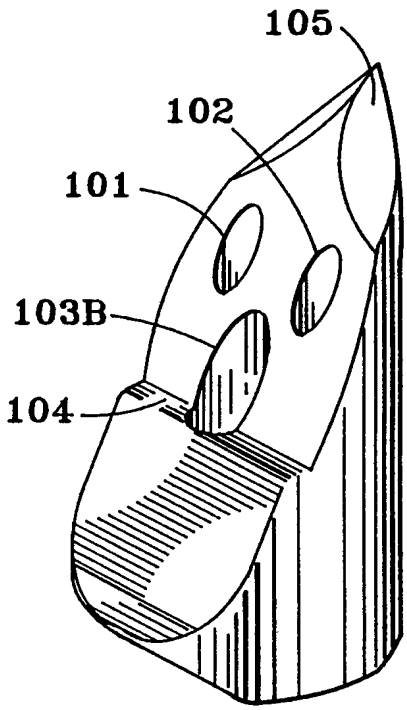


FIG. 38

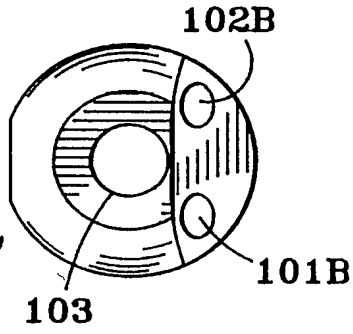


FIG. 37

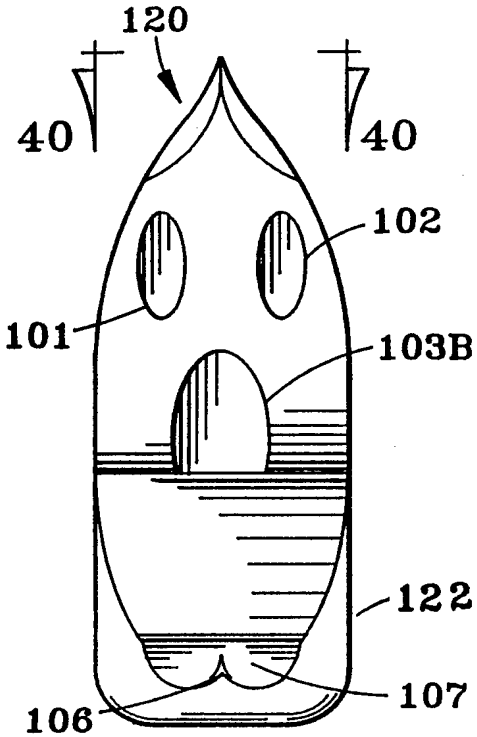


FIG. 39

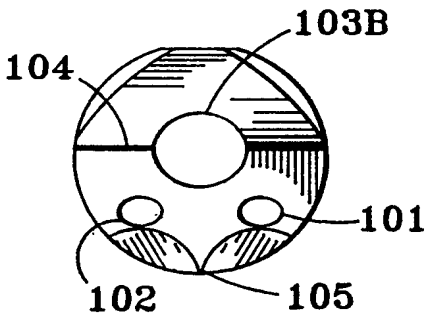


FIG. 40

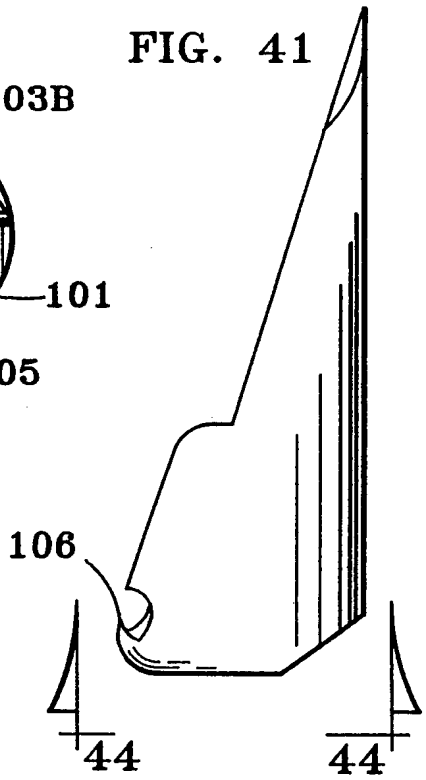


FIG. 41

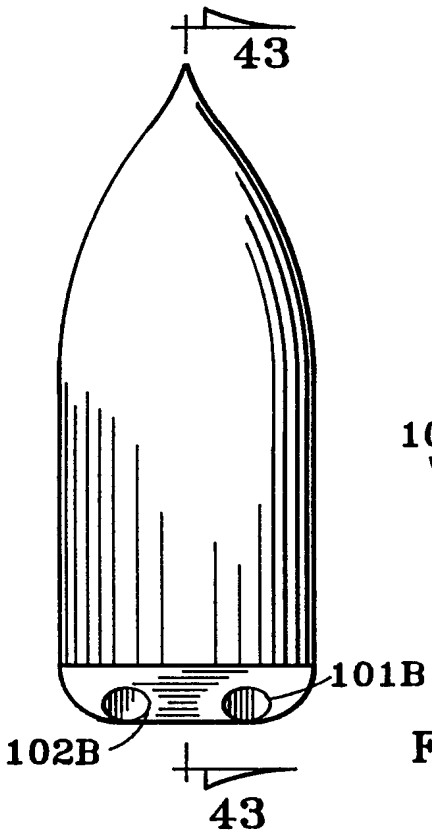


FIG. 42

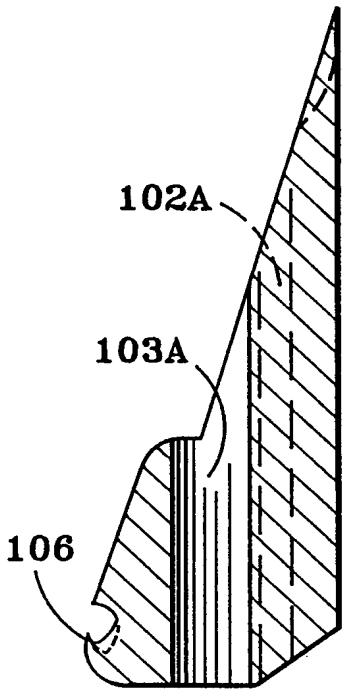


FIG. 43

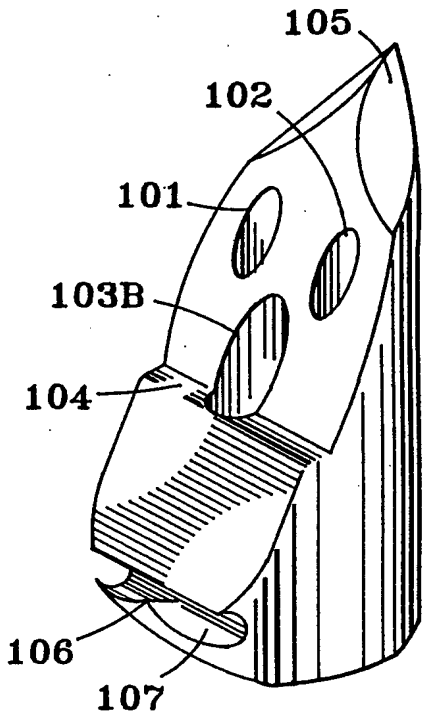


FIG. 45

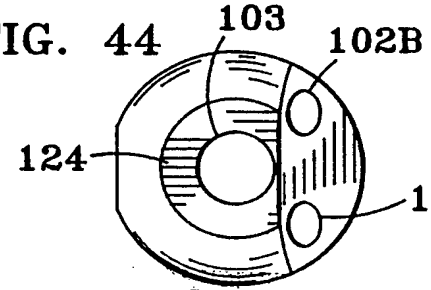


FIG. 44

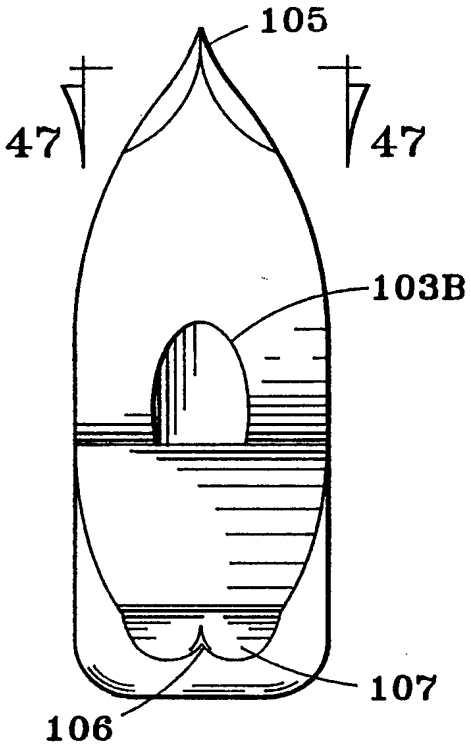


FIG. 46

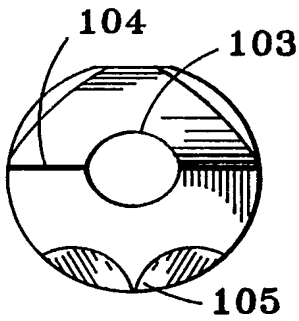


FIG. 47

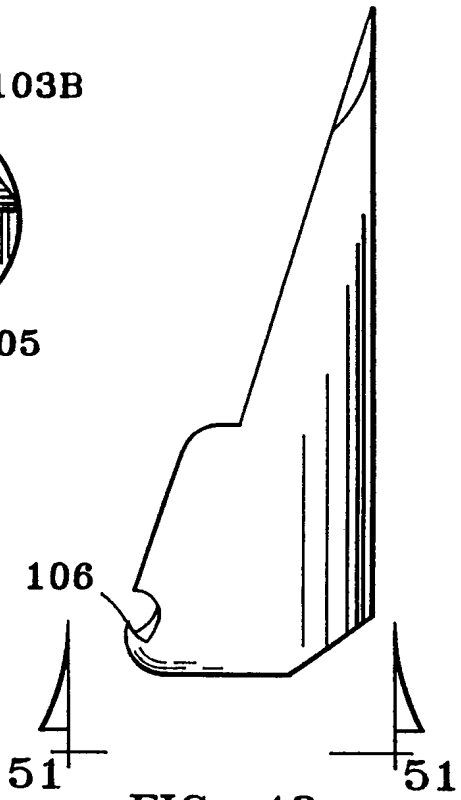


FIG. 48

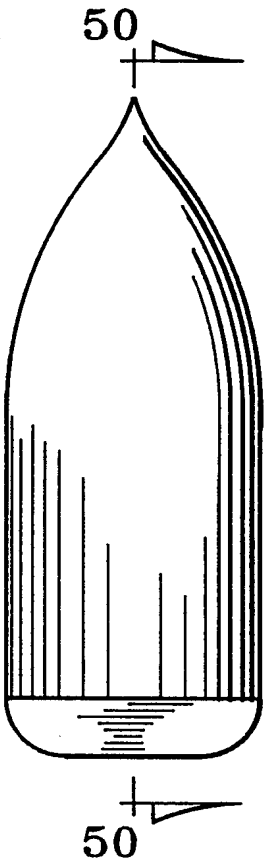


FIG. 49

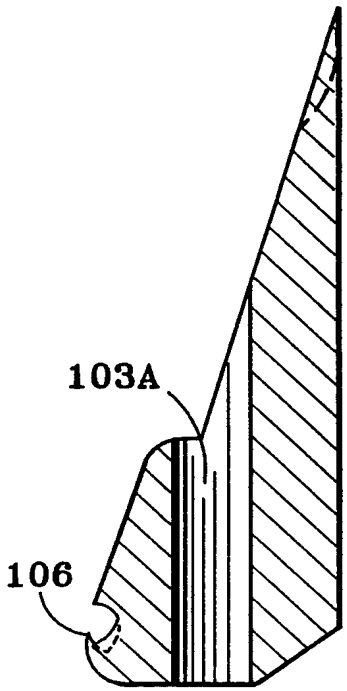


FIG. 50

FIG. 51

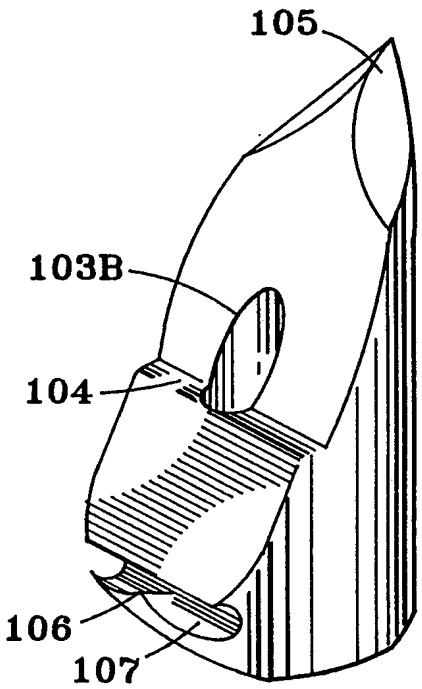
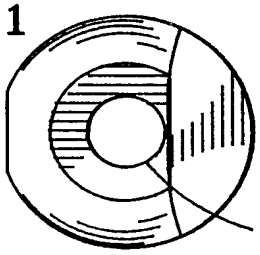


FIG. 52



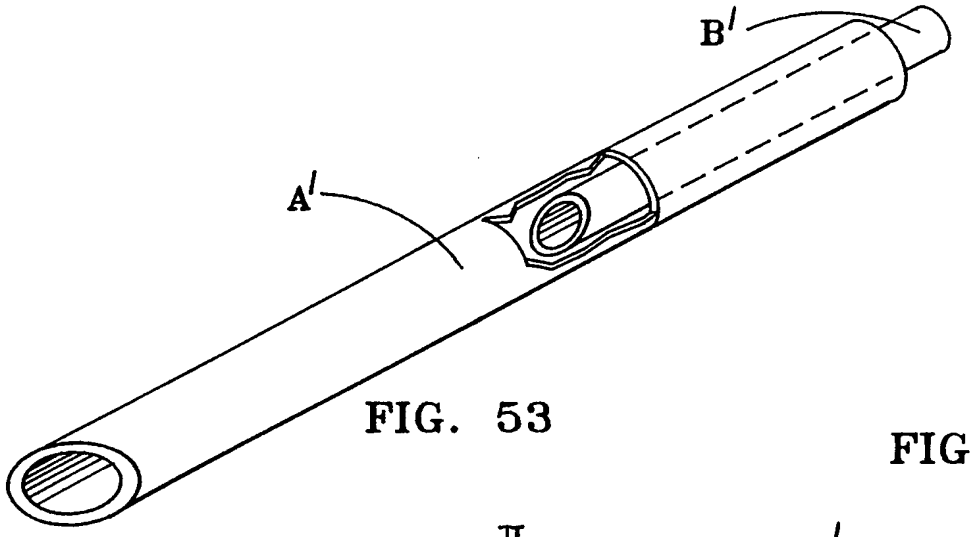


FIG. 53

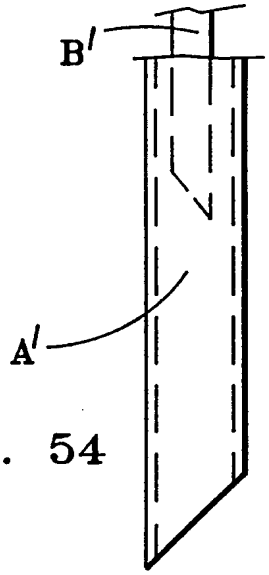


FIG. 54

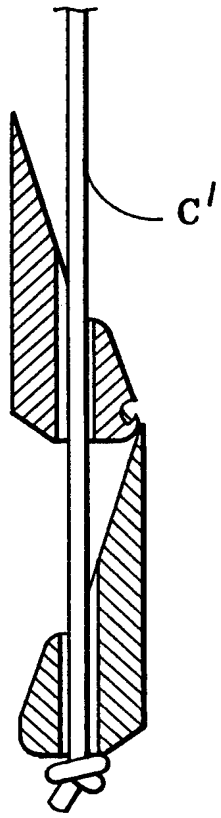


FIG. 55

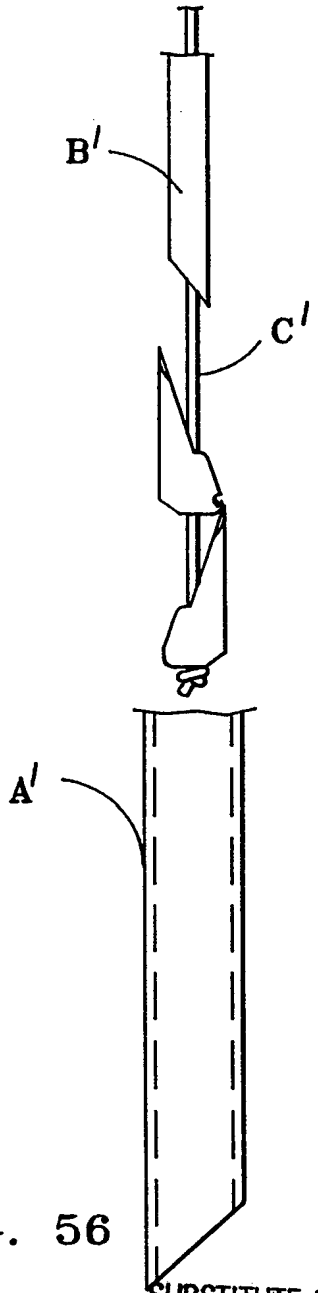


FIG. 56

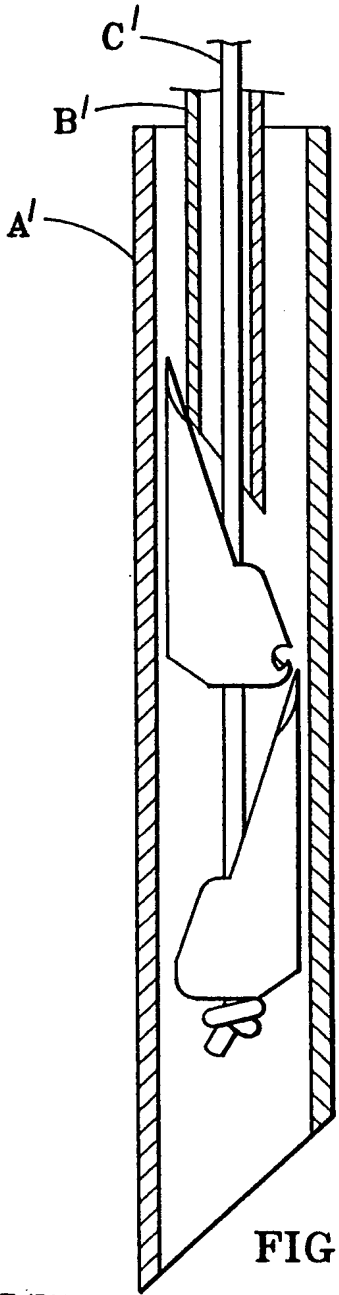


FIG. 57

FIG. 58

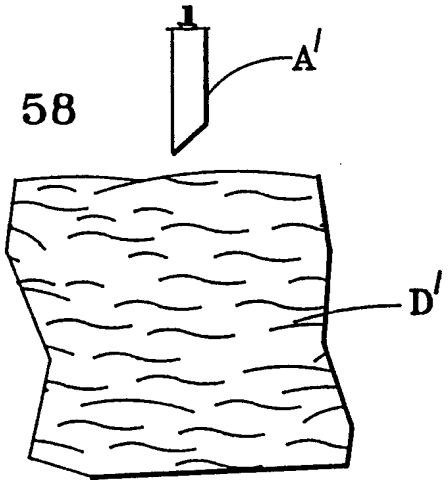


FIG. 59

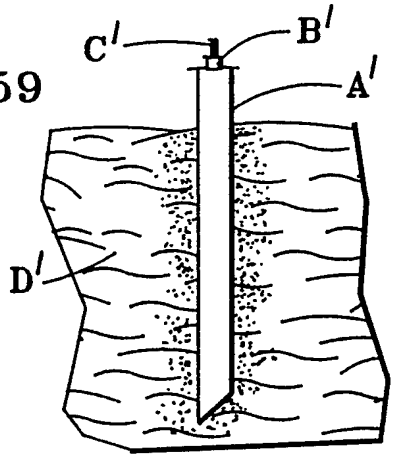


FIG. 60

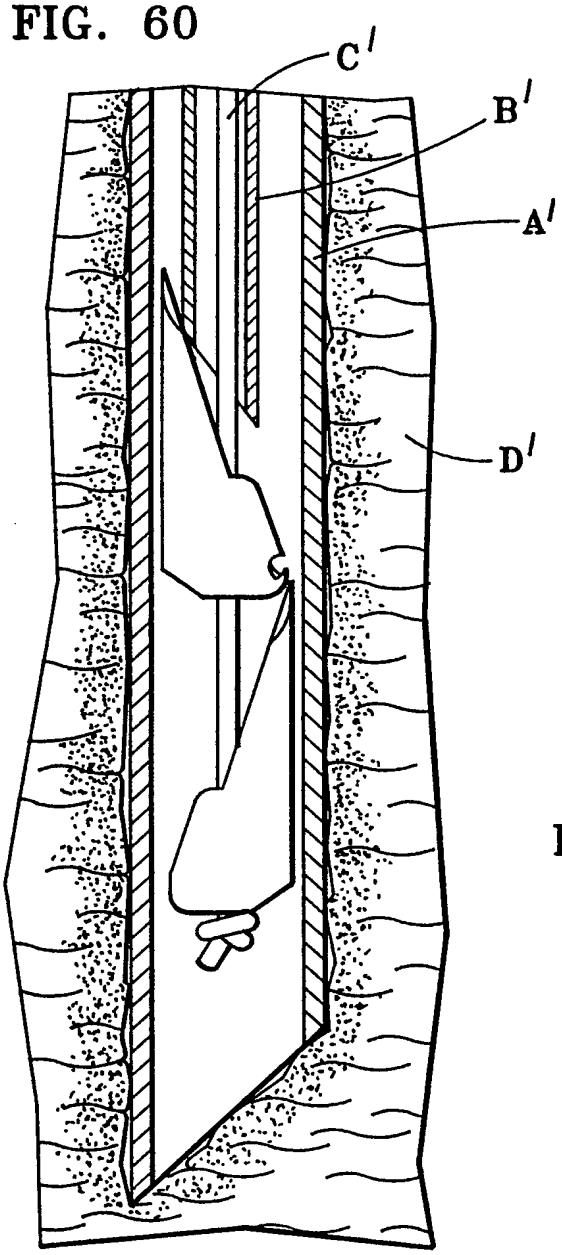


FIG. 61

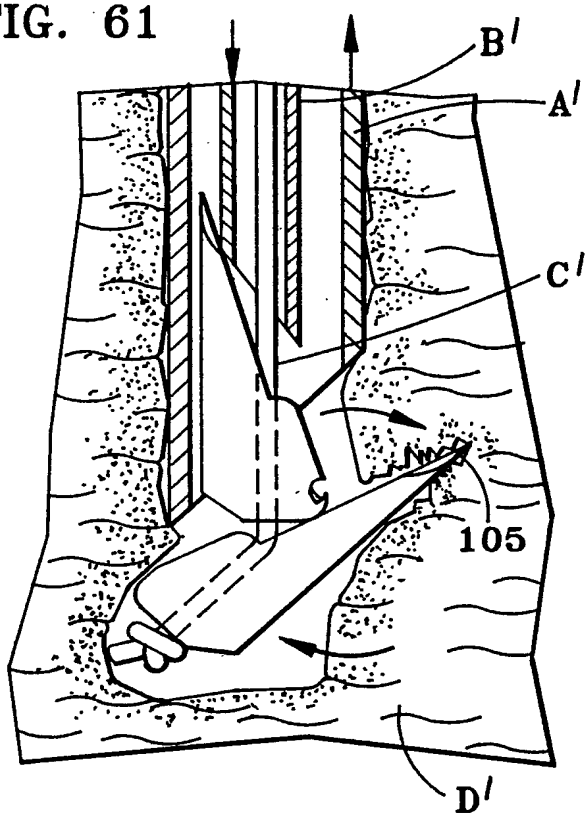
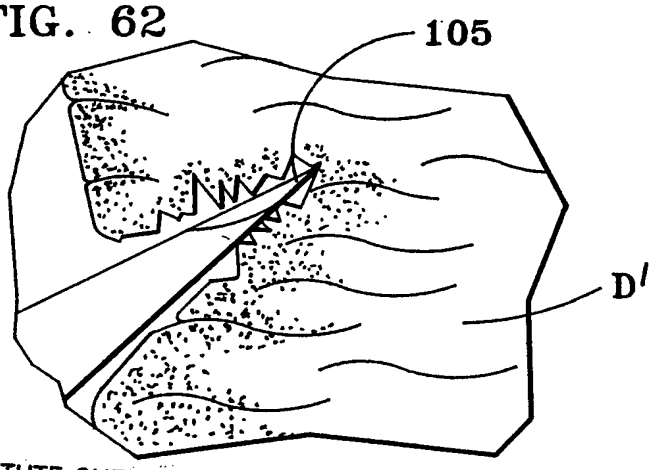


FIG. 62



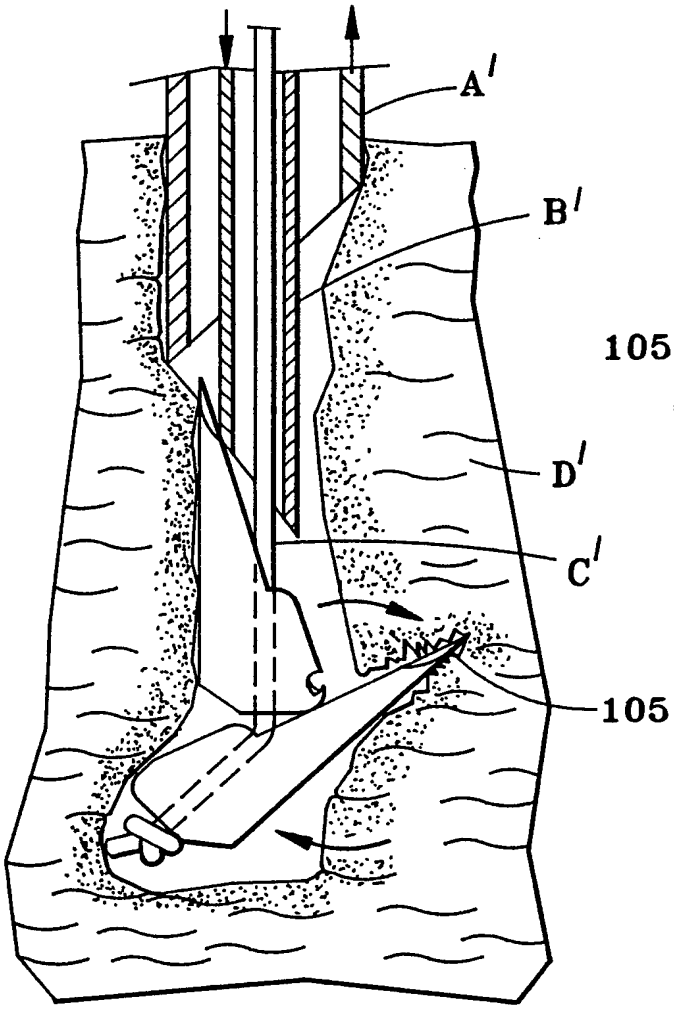


FIG. 63

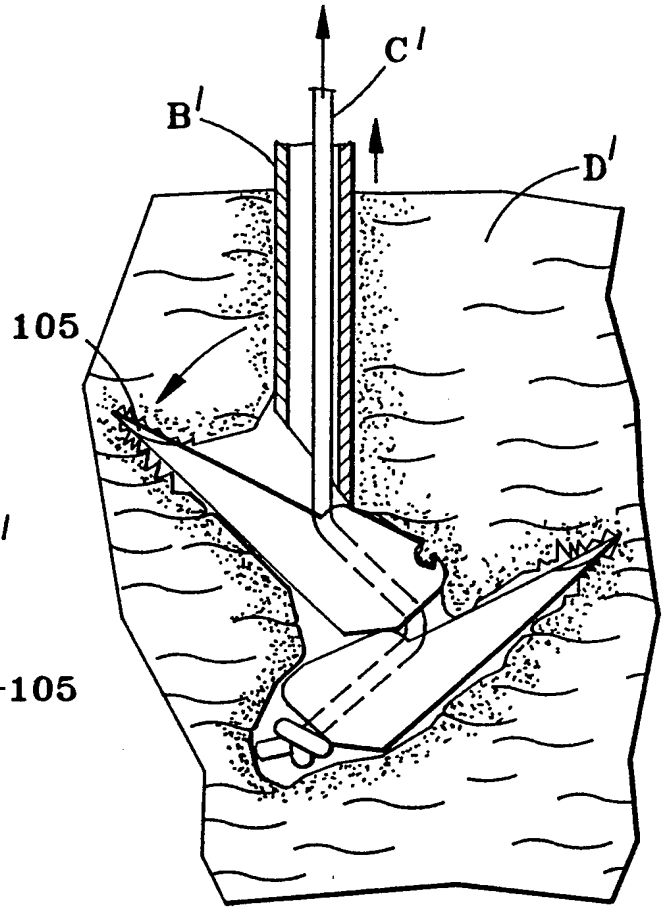


FIG. 64

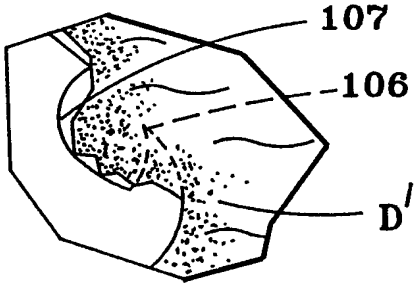


FIG. 65

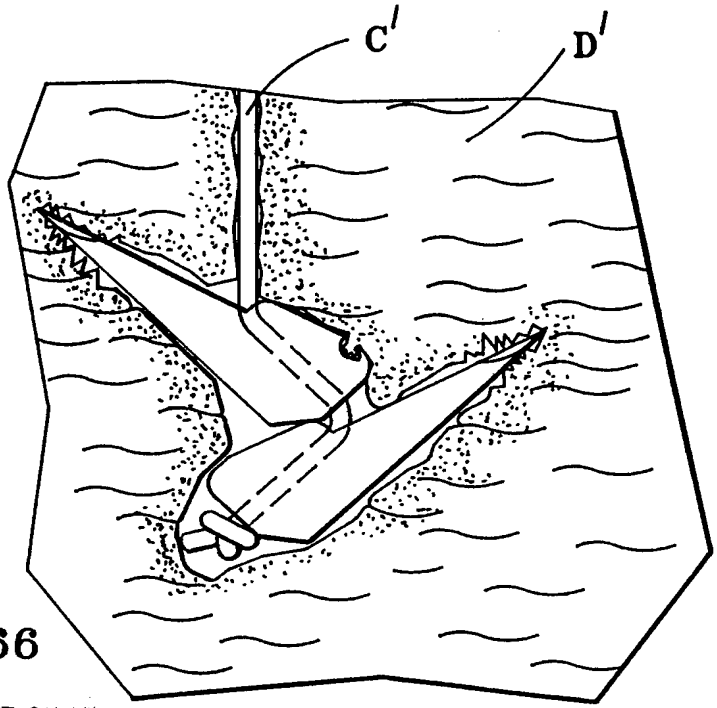


FIG. 66

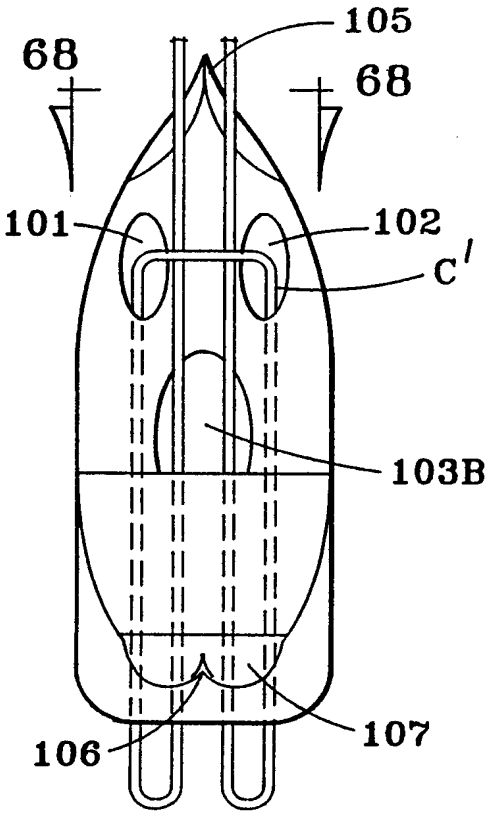


FIG. 67

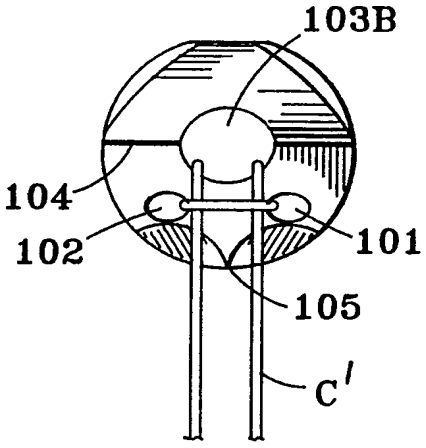


FIG. 68

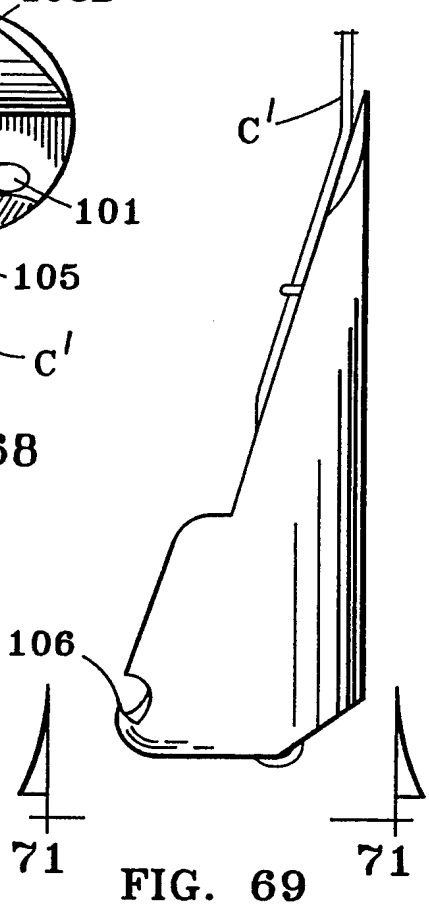


FIG. 69

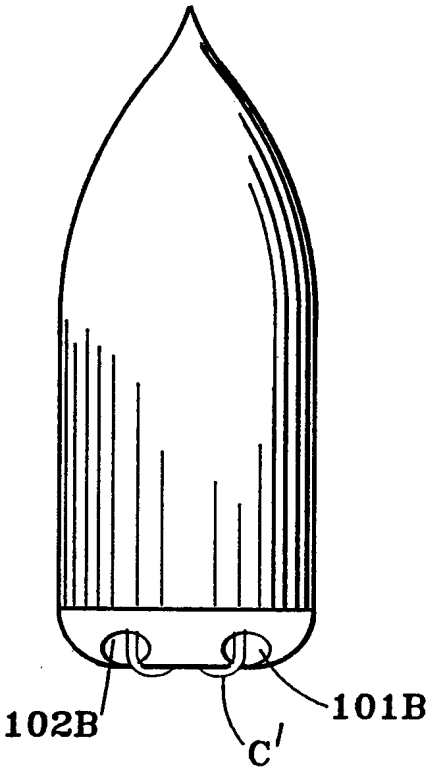


FIG. 70

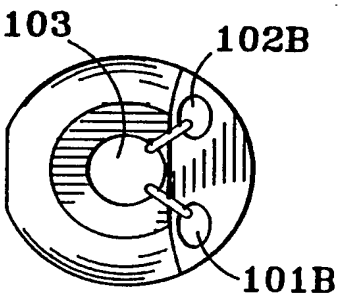


FIG. 71

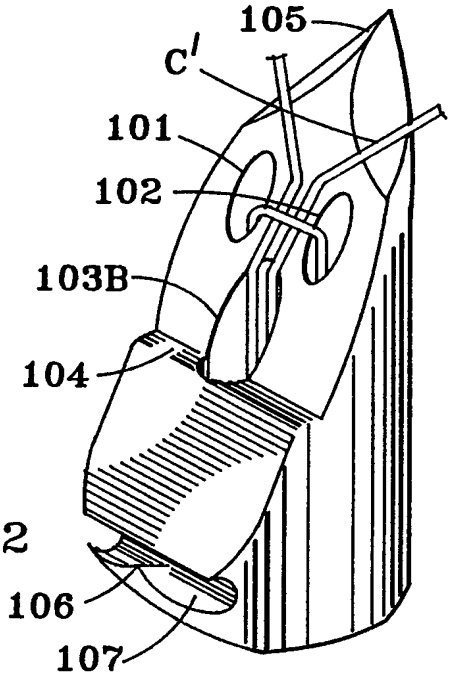


FIG. 72

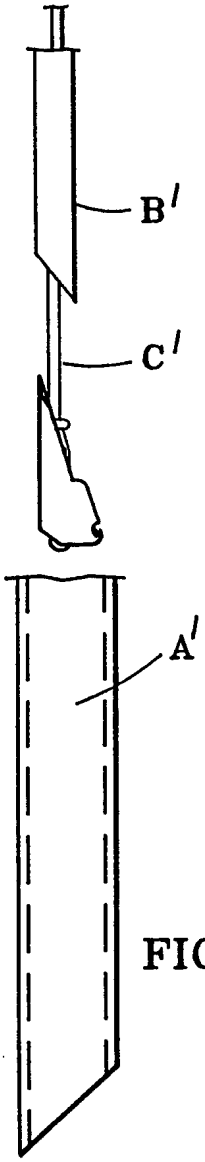


FIG. 73

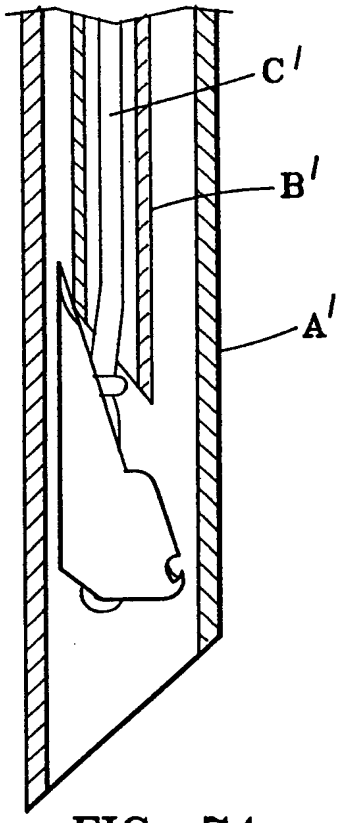


FIG. 74

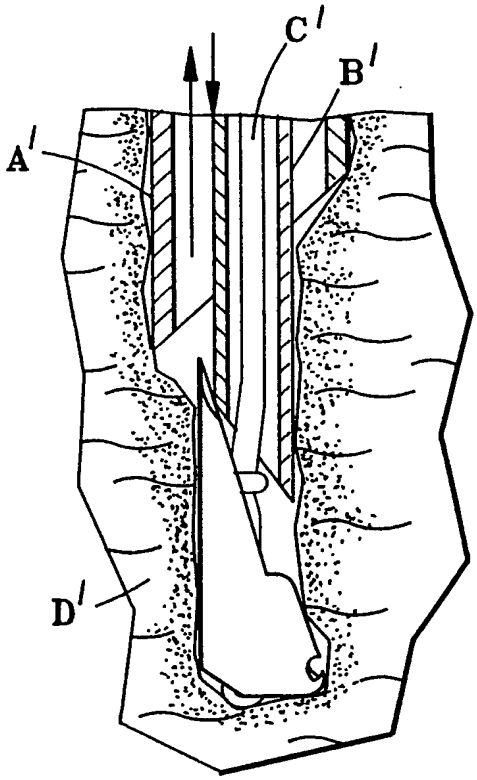


FIG. 75

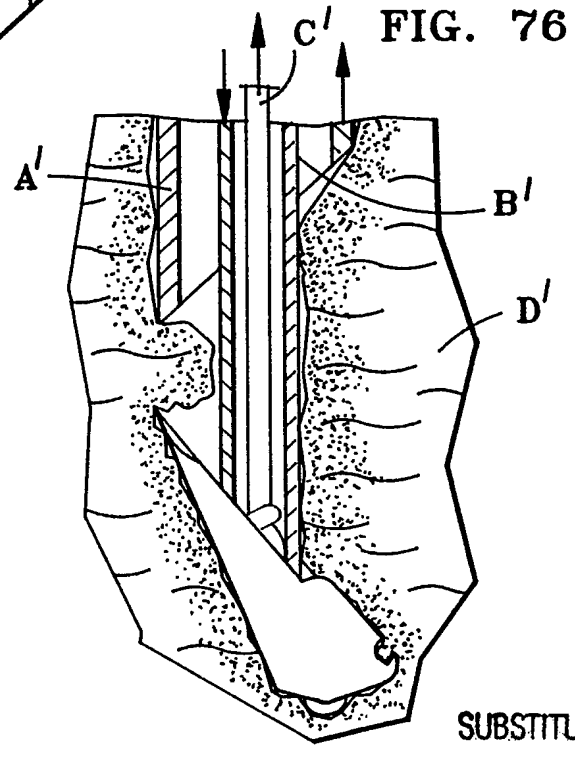


FIG. 76

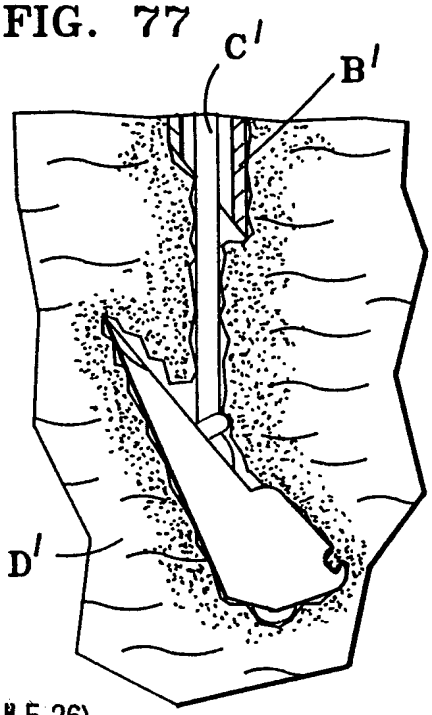


FIG. 77

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 94/12389

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE,U,89 11 360 (MECRON MEDIZINISCHE PRODUKTE) 30 August 1990 see page 4, line 14 - page 6, line 7; figures	1,5
A	EP,A,0 317 406 (LABOUREAU) 24 May 1989 see abstract; figures	1,3
A	US,A,5 037 422 (HAYHURST) 6 August 1991 see abstract; figures cited in the application	1,3,6
A	EP,A,0 464 480 (AMERICAN CYANAMID COMPANY) 8 January 1992 see abstract; figures 1,2,5	8,10,11, 13

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 February 1995	08. 03. 95

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Klein, C

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 94/12389

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO,A,87 01270 (ACUFEX MICROSURGICAL) 12 March 1987 see claims 1-3; figures 1,4-6,9	8,10
A	US,A,4 946 468 (LI) 7 August 1990 see claims 1-5; figures 1,2,10-17	8-13
A	US,A,4 898 156 (GATTURNA) 6 February 1990 see figures 1-17 cited in the application	8,9,11
A	US,A,5 203 787 (NOBLITT) 20 April 1993 see abstract; figures	8,10
P,X	US,A,5 324 308 (PIERCE) 28 June 1994 see the whole document	1-7
A	US,A,5 176 682 (CHOW) 5 January 1993 cited in the application	

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US 94/12389

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
DE-U-8911360	30-08-90	NONE		
EP-A-0317406	24-05-89	FR-A-	2623082	19-05-89
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US 94/12389

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US-A-5203787	20-04-93	NONE	
US-A-5324308	28-06-94	NONE	
US-A-5176682	05-01-93	NONE	